Exhibit 51

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

IN RE JOHNSON & JOHNSON TALCUM POWDER PRODUCTS MARKETING, SALES PRACTICES, AND PRODUCTS LIABILITY LITIGATION ***THIS DOCUMENT RELATES TO*:** ***All Cases***	**MDL NO. 16-2738 (FLW) (LHG)**

THIRD AMENDED EXPERT REPORT OF REBECCA SMITH-BINDMAN, MD

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The Relationship Between Exposure to Perineal Talc Powder Products and Ovarian Cancer

Third Amended Expert Report
May 2024

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I. Executive Summary

Substantial evidence supports a strong positive statistically significant association between ovarian cancer and genital exposure to talcum powder products. Regular exposure to talcum powder products causes ovarian cancer in some women. Talc is a naturally occurring mineral used in cosmetic products because of its desirable chemical properties such as being soft and absorbent. Women who have had regular exposure of the genitals (specifically the perineal region from the pubic area to the anal area) to talcum powder products are at increased risk of developing invasive ovarian cancer, in particular serous cancer, the most common and most lethal form of ovarian cancer. In the United States, a substantial portion of women report having ever used talc powder products at some point in their life, and the most commonly reported frequency of talcum powder product use is daily. Women who use talcum powder products regularly significantly increase their risk of developing ovarian cancer.

I was asked to review the medical and scientific literature regarding the relationship between genital talcum powder product use and ovarian cancer and determine whether the relationship is causal. For this report, and the analyses it contains, I applied the same methodology with the same scientific rigor that I use in my research and clinical practice. I reviewed 49 relevant publications presenting scientific data on the association between ovarian cancer and exposure to talc powder products including 4 cohort studies (5 publications), 11 systematic reviews, 4 studies that pooled data from multiple individual studies, and 30 case-control studies (one study contributes to two categories). I also read numerous detailed and comprehensive review articles on ovarian cancer and gynecology and carcinogenesis such as completed by Health Canada, systematic reviews on related topics such as those completed by the International Agency on Research on Cancer (IARC) on asbestos and talcum powder, and innumerable research and review articles that focused on in vitro studies that elucidate key biological aspects of cancer development and progression that would be promoted through exposure to talcum powder products. I also completed my own review of the published literature specifically focused on the regular use of talcum powder products and risk of ovarian cancer and that prompted a new systematic review with a focus on women who are frequent users of talcum powder products.

After reading, evaluating, and summarizing these publications, in my expert opinion, I believe, and do not have any uncertainty, that regular exposure to talcum powder products increases a woman's chance of developing epithelial ovarian cancer. In my expert opinion, regular exposure to talcum powder products causes ovarian cancer in some women. My review of the studies and systematic reviews published since my prior reports reaffirm my opinions.

Quantifying the magnitude of the association is more difficult than establishing the association. The magnitude of the association will vary by demographic factors, reproductive factors, and whether women have other underlying ovarian cancer risk factors and exposures. With that caveat, **it is my opinion that women exposed to perineal talc powder products on a regular basis have about a 50% increase in their subsequent risk of developing invasive serous ovarian cancer**, compared to women who do not regularly use talc and even after accounting for other ovarian cancer risk factors. This assessment is supported by existing publications and my own systematic quantitative review addressing exposure to talc powder products as a risk factor for ovarian cancer. Talcum powder exposure is most clearly demonstrated to be associated with serous cancer and other epithelial cancer subtypes (in particular, clear cell and endometrioid carcinoma), but because these other cancers are less common, and because fewer studies have evaluated these cancers in sufficient numbers, quantifying the associations is more difficult. In my opinion, this risk is likely overall in approximately the same range as for serous cancer.

The epidemiological evidence documents a strong, positive association between exposure to talcum powder products and ovarian cancer and that regular exposure causes ovarian cancer. The epidemiological evidence does not provide the mechanism by which talc powder products increase ovarian cancer risk, nor does it confirm the specific component in talcum powder products that makes them carcinogenic- asbestiform talc, platy talc, asbestos, heavy metals and fragrances may all play a role. Nonetheless, the literature that I reviewed identified and strongly supported plausible biological mechanisms. Specifically, that exposure to talcum powder products leads to chronic inflammation and that the inflammation induces a strong biological response that results in the induction, promotion, and growth of cancer, along with inhibition of mechanisms that ordinarily control cell proliferation but are altered by talcum powder. Recent studies demonstrated in normal and ovarian cancer cell lines that talcum powder induces inflammation and alters the redox balance favoring a prooxidant state by inducing specific mutations in key oxidant and antioxidant enzymes, thereby explaining a mechanism by which talc can induce and promote ovarian cancer. Further, there is evidence that several highly carcinogenic agents are components of the talcum powder products. (Longo & Rigler report 2019) These include asbestos (present in many talc powder product samples based on recent testing) and asbestiform talc fibers (present in essentially all tested talc powder product samples), each classified as Group 1 human carcinogens by the International Agency for Research on Cancer (IARC). Lastly, I have seen evidence that talcum powder products contain numerous heavy metals such as, nickel, chromium, (Group 1 carcinogens) and cobalt (Group 2 carcinogen) according to IARC. These components are carcinogenic (cause cancer) and can contribute to the carcinogenicity of talcum powder products. Observational and experimental data confirm that talcum powder product particles applied to the perineum can reach the fallopian tubes and ovaries through the vagina, supporting that talc and asbestos particles/fibers applied to the perineum can deposit on the fallopian tubes and ovaries. Surgery that impedes the movement of particles from the perineum to the ovaries such as hysterectomy (uterine removal) or tubal ligation (tying or blocking the fallopian tubes to the ovaries), reduces the elevated risk of ovarian cancer. (Taher, 2019). This finding supports that local tissue response and inflammation in the fallopian tubes and/or ovaries from talcum powder products (with components), as well as cellular changes that are initiated in response to talc, causes the elevated ovarian cancer risk.

In summary, **from my review of the scientific literature, it is my opinion that genital exposure to talcum powder products is an actionable and causative risk factor for ovarian cancer.** As a physician involved in women's health issues, I view talcum powder usage as a modifiable "lifestyle" risk factor that should be avoided because of the substantial risk to health and lack of therapeutic benefit. An elevated risk of 50% is significant and results in a large number of unnecessary ovarian cancers given the large number of women exposed. Depending on estimates of how many women regularly use talcum powder products, between 5% and 23% of all ovarian cancers are likely caused by the use of talcum powder products. These cancers can be prevented if women do not use talcum powder products.

II. Qualifications

<u>Education and Employment</u>

I am a professor of Epidemiology and Biostatistics, Obstetrics, Gynecology and Reproductive Medicine, and Health Policy at the University of California San Francisco (UCSF) School of Medicine and am the Director of the Radiology Outcomes Research Laboratory (RORL). I graduated from Princeton University with honors with a degree in structural engineering (with combined majors in engineering and architecture) and attended UCSF medical school. My training after medical school included an internship, radiology residency, and clinical fellowship in women's health and a research fellowship in epidemiology and biostatistics in the UCSF Departments of Medicine and Epidemiology and Biostatistics.

I am a clinician-scientist. My clinical work for the majority of my career included one day a week working clinically in the Department of Radiology and Biomedical Imaging, with a focus on women's health imaging in the ultrasound section. A large proportion of the work in ultrasound is focused on the diagnosis of ovarian disease (cancer and other functional issues). I run the UCSF Radiology Outcomes Research Lab, spending most of my time on clinical research and leading large epidemiological studies. I teach in the UCSF School of Medicine to first- and fourth-year students and in courses based in the Department of Epidemiology and Biostatistics.

Research Expertise

My research expertise is in epidemiology, outcomes research, comparative effectiveness, health services research, and dissemination and implementation sciences. My epidemiological studies have evaluated the quality, use, accuracy, predictive value, and impact of diagnostic testing on patient health. I have measured the risks and benefits of medical imaging in different contexts and different populations. Much of the research is in women's health, including diagnoses of cancers including ovarian, endometrial, thyroid and breast. I have led many large, multi-institutional NIH or other federally funded research projects. These projects are typically collaborative, involving researchers and clinicians with diverse expertise including radiology, obstetrics and gynecology, medicine, biostatistics, epidemiology, economics, demography, social sciences, medical informatics, radiation science, and dissemination and implementation science.

I have been a prolific researcher. I have led projects funded by more than 60 million dollars in research grants—almost entirely focused on cancer diagnosis and cancer prediction. The research has been published in the most prestigious medical journals including the *New England Journal of Medicine*, *Annals of Internal Medicine*, *Journal of the American Medical Association*, *Journal of the American Medical Association Internal Medicine*, *Journal of the National Cancer Institute*, *Obstetrics and Gynecology*, and the leading radiology specialty journals such as *Radiology* and *Journal of the American College of Radiology*.

Knowledge of Relevant Study Designs

Several of my published studies have been systematic, meta-analytic, quantitative reviews of the published literature. Meta-analyses review existing evidence on a topic and summarize and quantitatively re-analyze data from earlier studies. My systematic reviews have focused on the diagnoses of endometrial cancer, breast cancer, and a range of birth defects including trisomy 21 (Down syndrome) and trisomy 18 (Edwards Syndrome). Many of my reviews were published in prestigious medical journals, reflecting their scientific rigor based on an in-depth understanding of how to combine and review results from different studies in a scientifically valid and reproducible way.

Several of my recent research projects quantified the variation in radiation dose associated with medical imaging and the expected impact of this variation on cancer outcomes. This work has brought attention to the need for better standards in medical imaging. I have led and am now completing two large, multi-institutional epidemiological projects on medical radiation funded by the National Institutes of Health. One project involves collected radiation dose measures associated with computed tomography (CT) imaging from more than 165 hospitals and imaging facilities in the United States, Europe, and Asia and tested the impact of providing feedback and education to radiologists on average and high doses. The second project is a multinational epidemiological study on childhood cancer. This project is assessing the risk of cancer associated with medical imaging among around 3 million children and 1 million pregnant patients after accounting for a range of other cancer risk factors. The study will be the first to quantify the risk of medical imaging including CT among a large group of patients and uses novel methods to accurately estimate radiation dose from imaging. I am also

currently completing a large, randomized trial to understand the best strategy for the surveillance of pulmonary nodules.

I have expertise in a range of research study designs. The projects I currently lead (each funded by the National Institutes of Health or the Patient-Centered Outcomes Research Institute for between 9 - 15 million dollars each) have designs selected to be appropriate for the research question. For example, the study assessing the risk of cancer from medical imaging uses a *case-control study design*, *in which data are collected on a group of patients and those with a condition (cases), are matched to similar patients without the condition (controls)*. Matching people with a disease to people of similar age, gender, and other factors who do not have the disease allows researchers to determine if circumstances such as exposure to a potential toxin influence disease development.

My project on medical imaging and medical radiation uses a *cohort design*, *comparing groups of people (cohorts) in a population, some exposed to a potential disease agent and some not exposed*, to see if the agent influences disease. My study on reducing radiation doses from CT uses a *randomized controlled design*, *in which individual patients are randomly assigned to different treatments* so their effectiveness can be compared. I am studying lung nodules using a *cluster-randomized controlled trial design that randomly assigns groups of people in similar circumstances (for example because they all see the same doctor) to different treatments* so the effects of the treatments can be compared.

I have a deep understanding of how epidemiological studies are conducted. I understand what study designs are suitable to particular datasets, populations, and research questions and the advantages and disadvantages of each design. This is relevant as no single study design is "best;" there are strengths and weaknesses of each. The most appropriate and valid study design varies based on the research question being asked.

Experience as a Medical Expert

For the National Academy of Medicine, I have contributed to several reports, including Saving Women's Lives (2004), Improving Mammographic Quality Standards (2005), and Breast and the Environment: A Life Course Approach (2012), for which I wrote a review on the association between radiation exposure and breast cancer (Appendix). In addition to this research, I am actively involved in raising awareness of the need for better standards and greater safety around medical imaging, in particular related to radiation exposure. I have spoken at the US Food and Drug Administration, testified before the US Congress on several occasions, and worked with leading professional societies to focus attention on improving medical imaging safety. I have written several quality measures on radiation dose adopted by the National Quality Forum and developed educational tools to help physicians and patients understand the importance of minimizing radiation exposure from imaging.

Prior to providing my opinions on the association between talcum powder products and ovarian cancer, I had not reviewed the relevant literature and had not published in this area. As a result, I brought an unbiased perspective to my review. This report reflects my review of medical and scientific publications in this area (overviews and scientific studies) and review of documents shared with me by the lawyers who engaged me for this task.

III. Background: Ovarian Cancer and Talc as a Modifiable Risk Factor

Ovarian Cancer

Ovarian cancer is the seventh most common cancer in women and the fifth leading cause of cancer deaths in the United States.(Torre et al. 2018) In 2023, 19,710 women are expected to receive a new diagnosis of ovarian cancer and 13,270 women will die from it. (American Cancer Society 2023) Overall, about 1 in 78 women (1.3%) will be diagnosed with ovarian cancer in their lifetime and around 1 in 108 will die of it. In 2020, 236,511 women were living with ovarian cancer. (SEER Cancer Statistics Review 2020) Most cases occur among older women; the median age at diagnosis is 62, although this varies by ovarian cancer type. (SEER Cancer Statistics Review 2018) Ovarian cancer is frequently diagnosed at a late stage, when a cure is unlikely. Because so many ovarian cancers are diagnosed at a late stage, the overall mortality rate is high, and the overall 5-year survival is poor. With the poor prognosis and absence of a reliable screening test to find ovarian cancer early, it is a highly feared cancer for women and their physicians alike.

Histologic types Cancers are classified by histologic type, meaning the type of cells that are involved. Understanding ovarian cancer histologic types is important because the risk factors, etiology and genetics of ovarian cancer can vary by histological type. Therefore, the importance of talcum powder products as a risk factor or cause can also vary by type. Ovarian cancers (epithelial and non-epithelial) are a heterogeneous group of malignancies that vary in their pathological appearance, molecular biology, risk factors, etiology, and prognosis. (Torre et al. 2018) Epithelial ovarian cancers have several histologic types; most fall into a small group of more common types including serous, endometrioid, clear cell and mucinous. About 90% of ovarian cancers are epithelial (meaning they arise from cells on the surface of the ovary or fallopian tube) and the most common type of epithelial cancer is serous carcinoma. Serous is not only the most common type of ovarian cancer, it is also the most lethal type of ovarian cancer. Further, it is the type of cancer that pathologists can most consistently, reliably, and reproducibly diagnose. Thus, epidemiological studies will have the greatest ability to document a clear association between serous ovarian cancer types and talcum powder products if a connection exists. It is also the subtype that has been studied most from a molecular and pathologic research standpoint.

Table 1. Histologic Types of Ovarian Cancers Diagnosed Over 15 Years at the KP Washington (JAMA Internal Medicine)

Histologic Type	Number	Percent of Total Cancers
Papillary serous cystadenocarcinoma	52	36.6
Endometrioid carcinoma	17	12.0
Serous cystadenocarcinoma	15	10.6
Clear cell adenocarcinoma	12	8.5
Adenocarcinoma, NOS	11	7.7
Mucinous adenocarcinoma	7	4.9
Mixed cell adenocarcinoma	3	2.1
Serous surface papillary carcinoma	3	2.1
Granulosa cell tumor	3	2.1
Carcinoma, not otherwise specific	2	1.4
Mucinous cystadenocarcinoma	2	1.4
Mucinous cystic tumor of borderline	2	1.4
Carcinoma in situ	1	0.7
Squamous cell carcinoma	1	0.7
Papillary adenocarcinoma	1	0.7
Papillary serous cystadenoma, borderline	1	0.7
Adenocarcinoma with squamous meta	1	0.7
Granulosa cell tumor, malignant	1	0.7
Endometrial stroma sarcoma	1	0.7
Mullerian mixed tumor	1	0.7
Carcinosarcoma	1	0.7
Carcinosarcoma, embryonal	1	0.7
Teratoma, malignant	1	0.7
Astrocytoma	1	0.7
Marginal zone B-cell lymphoma	1	0.7
Total	**142**	**100**
Summary		
Serous carcinoma	70	49.3
Endometroid carcinoma	17	12.0
Clear cell carcinoma	12	8.5
Mucinous carcinoma	9	6.3

My research group reported on the ultrasound appearance of ovarian cancers among a large cohort

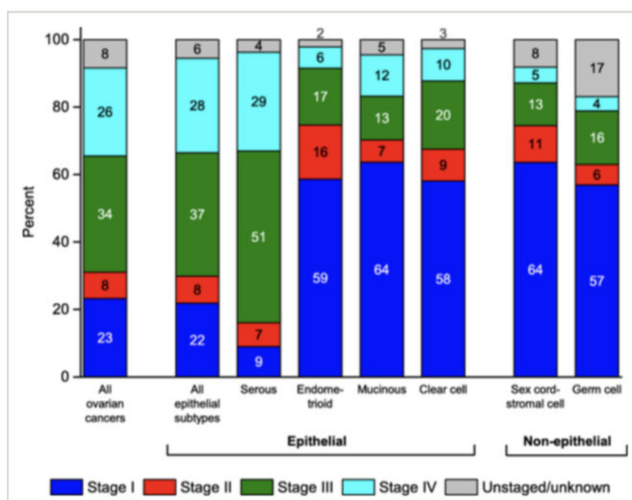
of women. The purpose of this cohort study was to quantify the risk of malignant ovarian cancer based on ultrasound findings. We described 142 new ovarian cancer cases in a population of 500,000 women enrolled in Kaiser Permanente Washington, an integrated health plan, between 1997 and 2008, including 72,093 women who underwent pelvic ultrasound. The distribution of cancer histological types is in Table 1. Serous carcinoma was the most common cancer type: In our cohort, it was 50% of the ovarian cancers. Serous carcinoma has the worst prognosis of the ovarian cancer types. Its high frequency and poor prognosis contribute to the high mortality rate for ovarian cancer overall. The other common histological types of ovarian cancer were endometrioid (12% in our data), clear cell (8.5% in our data), and mucinous (6.3% in our data). (Smith-Bindman et al. 2019)

Ovarian cancer types have large differences in stage of diagnosis (a strong predictor of survival) and prognosis independent of stage. The 5-year survival by histological type is in Table 2. Serous cancer is the most frequent and most aggressive, with an overall 5-year survival of 43% as compared with 82% for endometrioid. The survival is strongly influenced by stage at diagnosis, with higher stage numbers indicating more advanced stage. (Torre et al., 2018) Most serous carcinomas are diagnosed at stage III (51%) or IV (29%) (Figure 1), (SEER Cancer Statistics Review) for which 5-year survivals from the most recent data were 42% and 26%, respectively. These data reflect the aggressive nature of serous cancer. (Torre et al. 2018) In contrast, the majority (58% to 64%) of endometrioid, mucinous, and clear cell carcinomas are diagnosed at stage I, similar to nonepithelial tumors (Figure 1) . Consequently, the 5-year survivals are 82%, 71%, and 66%, respectively, for endometrioid, mucinous, and clear cell carcinoma. Thus, these cancers behave very differently, even though all are ovarian epithelial cancers.

Table 2. Percent of Women Surviving 5 Years After Diagnosis by Epithelial Ovarian Cancer Type. Data From 2008–2013.

	All epithelial types	Serous	Endometrioid	Mucinous	Clear cell	Sex cord-stromal	Germ cell
Stage							
All	47	43	82	71	66	88	94
Stage I	89	86	95	92	85	98	99
Stage II	71	71	84	69	71	84	93
Stage III	41	42	59	30	35	61	90
Stage IV	20	26	29	13	16	41	69

Figure 1. American Joint Committee on Cancer Sixth Edition Stage Distribution (%) for Ovarian Cancer by Histology, US, 2007-2013, SEER 18 Registries, NCI, 2017. This shows that serous cancers are more likely to be diagnosed at state III, IV (green and teal), compared with other tumor types.



This summary reflects our current knowledge about ovarian cancer histologic types and their associated prognoses. As research results are reported, our knowledge will evolve. For example, recent studies suggest we need to improve our ability to distinguish between high-grade serous and endometrioid carcinomas. Other results suggest that many ovarian mucinous carcinomas are actually gastrointestinal tumors that metastasized to the ovaries and this realization is affecting the reported rates of ovarian mucinous carcinomas (which are declining). (Torre et al. 2018, Yang

et al. 2013, Lee et al. 2003) The categorization of noninvasive tumors classified as borderline is also under investigation and a topic of discussion in the field. These noninvasive tumors have historically been considered in the spectrum of ovarian cancer that have less aggressive behavior. However, many previously described borderline cancers are now generally considered non-malignant.

In summary, when assessing the carcinogenicity of talcum power products, this should focus on invasive serous carcinoma as the most important cancer (based on prognosis) and the most reliable cancer to identify (based on histology and understanding of cancer behavior).

Additionally, over the last decade, there has been a growing of body of research suggesting that many ovarian cancers originate from cells in the distal portion of the fallopian tube. Because the pathogenesis, treatment, and prognosis of serous cancers of the fallopian tube, ovary, and peritoneum are similar, these are now typically considered as a single entity. (Lee et al. 2003) This consideration applies to the association with talcum powder product usage discussed in this report.

Risk Factors

Understanding ovarian cancer risk factors is important because analyzing the impact of talcum powder products exposure must consider *covariates, or other characteristics* that a woman might have that might also influence her ovarian cancer risk such as age, inherited genetic mutations, reproductive factors, or family history of cancer. Every risk factor does not have be considered to come to a valid conclusion; indeed, this is not realistic within the limitations of medical research, and the bias introduced by the exclusion or some risk factors will be small. However, crude analyses that look at the risk of ovarian cancer from talcum powder products without adjusting for any other risk factors must be considered cautiously. For that reason, statistical analyses of research results often adjust for *confounding factors or variables that are covariates that hinder accurate calculation of an association,* for example between talcum powder products and ovarian cancer.

Numerous risk factors are identified for ovarian cancer. (Lhereux 2019, IOM 2016, Mallen 2018) Unfortunately, few can be modified by therapies or lifestyle changes. Risk factors vary by histologic type (Wentzensen 2016) but those that increase risk of ovarian cancer include personal or family history of ovarian or breast cancer, inherited mutations including BRCA1 and BRCA2 (Bolton 2012, Weissman 2012, Hunn and Rodriguez 2012, Pal 2012, Gayther and Pharoah 2010) advanced age, white race, increased education, and endometriosis. Other factors that may increase ovarian cancer risk due to estrogen exposure include having no pregnancies or advanced age at first birth, obesity, and postmenopausal hormone therapy.(Lacey 2006, Trabert 2012, Lahmann 2010) Several factors are associated with reduced risk for ovarian cancer including breast feeding, multiple pregnancies, use of oral contraception, tubal ligation, and removal of uterus, fallopian tubes, or both. (Jordan 2010, Garg 1998, Lacey 2002, Seidman and Kurman 2002, Faber 2013; Taher 2019). Smoking is a possible risk factor for ovarian cancer, primarily mucinous subtype, although study results have not been consistent. (Faber 2013, Wentzensen 2016)

Risk factors vary by cancer type. For example, serous cancer is more strongly associated with reproductive risk factors than mucinous tumors (Risch 1996, Purdie 1995, Purdie 2003) and different histologic types have different molecular and genetic profiles. (Kurian 2005, Gates 2010, Gilks 2010) Serous tumors are more likely to have a cancer-promoting mutation in the p53 gene, whereas similar KRAS mutations are more common in mucinous tumors. Over time, the occurrence of ovarian cancer has changed, in part due to changes in risk factors. For example, small declines in the rates of endometrioid and serous cancer are attributed to declining use of hormone replacement among postmenopausal women.

Etiology: Origins, Causes, Development, and Inflammation

Our understanding of the etiology and course of ovarian cancer continues to evolve. (Lhereux 2019, Mallen 2018; IOM 2016) Hereditary genetic predisposition increases risk, but overall, accounts for only a small proportion of cancers. And even in women with hereditary genetic mutations, not all will develop ovarian cancer. The majority of ovarian cancers are now believed to arise in the distal portion of the fallopian tube. By convention, fallopian tube, ovary, and peritoneal cancers are considered as a single entity. The most widely accepted mechanism for initiation, promotion and progression of ovarian cancer is tissue inflammation leading to a series of responses that result in cancer.

There is very clear and extensive scientific literature describing the relationship between inflammation and cancer across many anatomic areas. Chronic inflammation, and even subtle, subclinical inflammation, is associated with an increased risk of cancer. (Balkwill and Mantovani 2001, Coussens and Werb 2002, Crusz and Balkwill 2015) Many inflammatory conditions predispose to cancer development. Diverse factors that lead to inflammation, infection, chemical exposures, physical agents, autoimmune factors, and even inflammatory reactions of uncertain etiology – can lead to an increase in cancer incidence. For example, there are well described and accepted causal pathways linking inflammation in the etiology of bladder cancer (schistosomiasis, toxic chemicals), cervical cancer (papillomavirus), gastric cancer (H Pylori), colon cancer (inflammatory bowel disease), liver cancer (hepatitis), mesothelioma (asbestos) and ovarian cancer (pelvic inflammatory disease and endometriosis). The biological pathways associated with inflammation include stimulation/interference with a range of biological responses that are involved in initiation of cancer, promotion of cancer, and progression of cancer. Oxidative stress resulting from inflammation can impact all stages of cancer development including cancer initiation (DNA is damaged by introducing gene mutations and structural alterations of DNA leading to inhibition of DNA repair and malignant transformation); promotion (which may be manifest as abnormal gene expression resulting in cell proliferation and decrease apoptosis) and progression (further DNA damage and enhancement of cell growth). (Reuter et al.2010, Savant 2018) Local inflammatory response can lead to signaling molecules such as cytokines, chemokines, prostaglandins, growth transcription factors, microRNAs having higher expression that can promote cancer development and can create a favorable microenvironment for the development and progression of cancer.(Fernandes et al. 2015) Inflammation impacts every step of tumorigenesis, from initiation through tumor promotion, and extending to metastatic progression. Similarly, the most compelling mechanism for the etiology of ovarian cancer is that of chronic inflammation and scarring in the ovary that leads to malignant transformation and cancer progression. This mechanism involves cell proliferation, oxidative stress, DNA damage and gene mutations. (Harper 2023, Emi 2021, Mandarino 2020, Fletcher 2019, Saed 2017, Saed 2010, Shan 2009, Ness 2000, Ness 1999) The microenvironment of ovarian cancer contains a broad spectrum of pro-inflammatory cytokines and chemokines contributing to the mechanism. (Freedman 2004) Recent studies have shown that in multiple different cell lines (including ovarian cancer cell lines) that talcum powder induces significant changes to key redox enzymes altering the inflammatory balance, enhances the prooxidant state, induces cell proliferation and reduction in apoptosis, and influences the epigenome and gene expression. (Harper 2023, Emi 2020, Fletcher 2019.)

There are many processes that can lead to inflammation and tumorigenesis and the exposure to talcum powder products is one such exposure that can strongly enhance the tumor promotion or progression as seen in in vitro and animal studies. For example, normal repeated ovulation leads to injury of ovarian epithelial cells and transformation to malignant cancer cells that can be enhanced by various factors such as talc or asbestos particles. Exposure to talcum powder products can induce the production of pro-oxidant enzymes and reduced production of antioxidant enzymes leads to malignant transformation. In support of inflammation from talcum powder products causing cancer, hysterectomy, or bilateral tubal ligation, which

would significantly limit ovarian exposure to inflammatory mediators, and toxins, is associated with reduced ovarian cancer risk.

Relationship Between Ovarian Cancer and Talcum Powder Products
The epidemiological evidence described in detail below demonstrates a strong and positive association between exposure to talcum powder products and ovarian cancer and that talcum powder products cause ovarian cancer. Although epidemiologic evidence alone does not provide a definitive mechanism or pathophysiological process that accounts for the increased risk, the evidence for inflammation as described above is very strong. Similarly, epidemiological evidence alone does not confirm the specific component or ingredient in talcum powder products that is responsible for its carcinogenesis. Nonetheless, several constituents within talc powder products are worth highlighting as they may be acting individually or together to create the carcinogenicity of talc powder products inasmuch as they are individually highly carcinogenic.

Why Talcum Powder Products were Initially Suspected as Causing Ovarian Cancer
In 1978 samples of commercial body powders were shown to contain asbestos silica minerals. Asbestos was a known carcinogen and about half of the powder samples contained respirable quartz, a lung carcinogen. Concerns were primarily raised that inhaled powder could cause lung scarring, lung cancer, or mesothelioma. In 1971, Henderson observed talc particles deeply embedded in ovarian cancer tissue. The authors noted the close association of talc to the asbestos group of minerals. (Henderson et al. 1971) Further concern was raised, in 1982 when a case-control study of ovarian cancer that collected information on talcum powder use reported an increased risk with perineal dusting.(Cramer et al. 1982) These findings were reported in widely circulated newspapers such as The Globe, raising concern that the powders were carcinogenic because of the contamination with asbestos, using the relationship between asbestos and lung cancer and mesothelioma as the basis for the concern.

Carcinomic of Constituents of Talc Powder Products
There are hundreds of different constituents and ingredients within talcum powder products in addition to platy talc. Many of these are Group 1 carcinogens (such as asbestos, talc fibers (fibrous talc), heavy metals, and some fragrance chemicals) that likely contribute to the carcinogenicity of the products.

Asbestos
Asbestos is the generic commercial designation for a group of naturally occurring mineral silicate fibers; serpentine mineral fibers are called chrysotile, and amphibole minerals include actinolite, amosite, anthophyllite, crocidolite and tremolites. Talc is formed by complex geological processes acting on pre-existing rock formations with diverse chemical composition. Small amounts of chrysotile (asbestos) may occur in these talc deposits. (Rohl et al 1976, Zazenski 1995) When talc is mined, it may contain asbestos fibers. (Zazenski et al.1995, Blount 1991) A study of 21 consumer talcum powders obtained from retail stores in 1971–1975 reported that 10 contained concentrations of asbestos fibers ranging from 0.2 to 14%. (Rohl et al. 1976, IARC 2010) Because of concern that asbestos was present in talcum powder products and the known carcinogenicity of asbestos, it has been reported that voluntary guidelines were established by the cosmetic industry in 1976 to limit the content of asbestos fibers in commercial talc preparations. While talcum powder products have long been believed to be free from asbestos based on this voluntary guideline, this is absolutely incorrect; talcum powder products have never been free of asbestos. (Longo & Rigler, 2019; Hopkins Dep. 2018; FDA Testing 2019) The data on its continued presences are strong. I have seen evidence of continued presence of asbestos in talcum powder products since 1976. For example, Longo & Rigler tested multiple samples provided by Johnson and Johnson and its talc supplier that were taken between the years 1960 through 2000 and the majority of sample are positive for asbestos. (Longo & Rigler 2019) The FDA

commissioned testing of samples from a Johnson's Baby Powder bottle purchased in 2018 and the outside lab found chrysotile asbestos and asbestiform talc.

Asbestos is a known and potent human carcinogen. Asbestos is highly carcinogenic to the lungs, lining of the lungs, and larynx. (IARC 2012) Asbestos is also highly carcinogenic to the ovaries. (IARC 2012, Acheson 1982, Wignall and Fox 1982, Germani 1999, Berry 2000, Magnani 2008, Reid 2008, Vasama-Neuvonen 1999, Langseth and Kjaerheim 2004, Pira 2005) Women working in asbestos-manufacturing industries have an increased risk of ovarian cancer. IARC reviewed the association between asbestos exposure and ovarian cancer in 2012. To assess the relationship, IARC reviewed data primarily from large epidemiological cohort studies of women who had occupational exposure to asbestos as well case-control studies on non-occupational exposure. The context and lengths of exposures varied, along with the type of asbestos fibers to which the women were exposed and the study designs and assessments. Nonetheless, the results were consistent. Most, but not all, were statistically significant and documented a strong and compelling causal association between exposure to asbestos and ovarian cancer, largely the result of the association from cohort studies of women with substantial occupational exposures. (Acheson 1982, Wignall and Fox 1982, Germani 1999, Berry 2000, Magnani 2008) **IARC concluded that there is sufficient evidence that asbestos is carcinogenic in humans (Group 1) and that asbestos causes cancer of the ovary**. This is the highest risk category. (IARC 2012) IARC also concluded that this categorization applied to all forms of asbestos and to talc containing asbestiform fibers (talc in an asbestiform habit or fibrous talc). Thus IARC concluded that fibrous talc is a Group 1 carcinogen. IARC also concluded that asbestos is carcinogenic based on animal studies. Camargo completed a systematic review of the relationship between women occupationally exposed to asbestos and ovarian cancer. (Camargo 2011) The authors found that of the 18 cohort studies the pooled standard mortality estimate for ovarian cancer was 1.77 (95% confidence interval, 1.37-2.28). The range in reported SMR values was 1.1– 5.4 across the included cohort studies and the most common values were 2–3. This study supports IARC's conclusion that exposure to asbestos causes ovarian cancer. To the degree that we now know talcum powder products contain asbestos fibers, this study also supports that talcum powder causes ovarian cancer.

However, IARC explicitly stated that the findings in this Monograph applied to all forms of asbestos, as well as asbestiform talc (fibrous talc or talc fibers). Thus IARC concluded that fibrous talc (ubiquitous in talcum powder products) is a group 1 Carcinogen even without invoking that talc powder products also contain asbestos.

I reviewed many publications and primary research studies, including experimental and basic science models showing molecular and genetic cancer-promoting changes to cells that occur from exposure to asbestos and other mineral fibers. Asbestos and other mineral fibers have been shown to be carcinogenic through a process involving persistent inflammation, oxidative stress, DNA damage, activation of intracellular signaling pathways, resistance to apoptosis, and stimulation of cell proliferation. (IARC 2012, Moller 2013, Mossman 2018)

I also strongly conclude that asbestos causes ovarian cancer.

Talc

Talc is the primary component of talcum powder products. The chemical structures of talc and asbestos can be similar. While talc particles are usually plate-like, talc can also grow as a fiber which is similar to the group of minerals called asbestos. Both are magnesium silicate and when talc has the fibrous form it is called asbestiform because of its similarity to asbestos. The form of the talc fibers is long and thin, with parallel bundles that are easy to separate from each other, and closely resembles the physical appearance of some

asbestos minerals. The histologic appearances of mesothelioma and ovarian cancer are similar. The known carcinogenicity of asbestos for lung, pleural, peritoneal, and ovarian cancer has led to the theory that the similarity in the fibers and the resulting cancers suggests that talc works mechanistically within the ovary to induce cancer in a way that is similar to how asbestos in the chest induces mesothelioma.

The female genital tract is open, with little barriers existing in the pathway from the perineum to the vagina, cervix, uterus, fallopian tubes and peritoneum and ovary. Early observations demonstrated talc particles in both malignant and normal ovaries establishing a route from the perineum to the ovary and shows that many women are exposed to talc. (Henderson 1971, Heller et al.1996, Sjosten 2004) Recent evidence has shown that talc particles in commercially available baby powder are similar in size and shape as the talc particles identified in pelvic tissues resected from ovarian cancer patients. (Johnson 2020). Using polarized light microscopy and scanning electron microscopy Johnson et. al. measured the size and shape of talc particles in samples of talc-containing baby powder (including samples of Johnson & Johnson's baby powder) and surgically resected pelvic tissues (hysterectomies) from 11 randomly selected talc-exposed patients with ovarian carcinoma. The talc particles found in resected tissues from ovarian carcinoma patients were similar in size and shape to the most abundant morphological class of particles in commercial baby powder samples: 77.7%– of particles in talcum powder have aspect ratio of 1–3.9 and area of 1–400 µm, whereas 83.5% of talc particles in pelvic tissues ovarian carcinoma patients have an aspect ratio of 1–3.9 and an area of 1–400 μm^2. Johnson et al. conclude that "this observation, combined with previous epidemiological literature and tissue-based analytical studies, provides further evidence that the small, isodiametric particles that dominate in commercial talc containing baby powder can migrate from the perineum and become lodged in distal structures in the female reproductive tract, where they may lead to an increased risk of developing ovarian carcinoma."

In 2006, the International Agency for Research on Cancer (IARC) reviewed the data on cosmetic (perineal) talc ("non-asbestiform") application and concluded that it is possibly carcinogenic to humans. (IARC 2010, Baan et al. 2006) This is not as strong a recommendation as they made for asbestos and ovarian cancer, but nonetheless is a strong recommendation. IARC classified genital-perineal use of talc-based powder as possibly carcinogenic. However, in the more recent IARC report (2012), they included both asbestos and asbestiform talc as carcinogenic to humans, as Group 1 carcinogens. (IARC 2012) They note that the most common route of exposure in the general population is perineal from use of cosmetic talcum powder products. IARC announced in 2019 that re-evaluation of the classification for domestic talc products is a high priority based on "new human cancer and mechanistic evidence." (IARC 2019.)

Exposure to talc particles can induce an inflammatory response, either directly at the ovary and ovary-fallopian tube juncture, causing local irritation from talc particulates or through more generalized peritoneal inflammation. The mechanism that can lead to cancer includes local irritation by talc fibers that disrupts the epithelial surface, increasing rates of cell division and DNA repair that can lead to mutations. Also increased are oxidative stress and cytokine production, indicating inflammation. Fibers that are incorporated into the epithelial cells enter ovarian tissue. This inflammation initiates a series of responses, supported by research, that promote cancer. (Harper et al. 2019, Savant et al. 2018) The reduction in the elevated risk of ovarian cancer from talcum powder exposure after hysterectomy or tubal ligation supports the mechanism by which local irritation and inflammation to the ovary from talc or asbestos causes an elevated cancer risk. Recent invitro research elucidates the cellular inflammatory changes, alteration of macrophages, and changes to the DNA and epigenetic expression, which in turn increase the likelihood of carcinogenesis. The research has also demonstrated direct transformation into cancer.

Macrophages are the first line of immune cells to clear foreign bodies from a cell, and direct studies have shown the negative impact of talc on normal macrophage function. Mandarino and colleagues recently tested the hypothesis that macrophage anti-tumor abilities are reduced and compromised by interaction with talc particles (2020). "The researchers tested the effects of talc vs. control particles on the ability of prototypical macrophage cell lines to curb the growth of ovarian cancer cells in culture in the presence of estrogen. They found that murine ovarian surface epithelial cells, a prototype of certain forms of ovarian cancer, were present in larger numbers after co-culture with macrophages treated to a combination of talc and estradiol than to either agent alone or control. Co-exposure of macrophages to talc and estradiol led to increased production of reactive oxygen species (which increase carcinogenesis and inflammation) and changes in expression of macrophage genes pertinent in cancer development and immunosurveillance. the authors concluded that the finding suggest that in vitro exposure to talc, particularly in a high-estrogen environment, may compromise immunosurveillance functions of macrophages." The same mechanism could apply in vivo to exposure to talc.

Emi and colleagues (2021) report a gene chip microarray profiling study and found that talc alone, and especially when combined with estrogen, induced substantially more gene expression changes in comparison to the control, a particle of similar size. The cellular pathways that were impacted were those involved in cellular proliferation, immune response and regulation, and enzymes and proteins of epigentic regulation. They subsequently tested the DNA methylation profiles and identified what they note as "vast epigenic changes in hundreds of loci" including in pathways involve in immune and inflammatory signaling. This provides evidence of the impact of these particles for initiating cellular changes that would lead to cancer.

Harper and colleagues recently found that exposure to talcum powder induces malignant transformation in normal human ovarian cells (2023). In their invitro study, ovarian epithelial cells and fibroblasts were treated with either talcum powder or titanium dioxide (a particulate control) at different concentrations for 72 hours before assessment with a cell transformation assay and p53 and Ki-67 immunohistochemistry. P53 gene codes for a protein that acts as a tumor suppressor, which means that it regulates cell division by keeping cells from growing and dividing too fast or in an uncontrolled way. ki-67 is a nuclear protein that is a marker of active cell proliferation. Harper found that treatment with talcum powder resulted in formation of colonies, indicating cell malignant transformation in a dose dependent manner in ovarian cell lines. No colonies formed in the untreated or control cells. Further the number of transformed cells were increased in a dose dependent fashion. Further, p53 mutant type as well as increased expression of Ki-67 were detected in ovarian cells when exposed to talcum powder demonstrated the genetic pathways for the malignant cellular transformation. The authors conclude that the findings represent a direct effect of talcum powder exposure that is specific to normal ovarian cells and further supports previous studies demonstrating an association between the genital use of talcum powder and an increased risk of OC.

Fletcher and colleagues undertook a study to identify the cellular effect of tac on normal and Epithelial ovarian cancer cells, and demonstrated that talc induces significant changes in key redox enzymes and enhances the prooxidant state in normal and EOC cells. (2019) This confirms the cellular effect of talc and provide a molecular mechanism linking genital use to increased ovarian cancer risk through oxidative stress and inflammation. "Using real-time reverse transcription polymerase chain reaction and enzyme-linked immunosorbent assay, levels of CA-125, caspase-3, nitrate/nitrite, and selected key redox enzymes, including myeloperoxidase (MPO), inducible nitric oxide synthase (iNOS), superoxide dismutase (SOD), catalase (CAT), glutathione peroxidase (GPX), and glutathione reductase (GSR), were determined. TaqMan genotype analysis utilizing the QuantStudio 12K Flex was used to assess single-nucleotide polymorphisms in genes corresponding to target enzymes. Cell proliferation was determined by MTT proliferation assay. In all talc-treated cells, there

was a significant dose-dependent increase in prooxidant iNOS, nitrate/nitrite, and MPO with a concomitant decrease in antioxidants CAT, SOD, GSR, and GPX ($P < .05$). Remarkably, talc exposure induced specific point mutations that are known to alter the activity in some of these key enzymes. Talc exposure also resulted in a significant increase in inflammation as determined by increased tumor marker CA-125 ($P < .05$). More importantly, talc exposure significantly induced cell proliferation and decreased apoptosis in cancer cells and to a greater degree in normal cells ($P < .05$). These findings confirm the cellular effect of talc and provide a molecular mechanism to previous reports linking genital use to increased ovarian cancer risk."

Heavy Metals

Talc powder products can contain Group 1 metals that are considered by IARC as carcinogenic to humans. (IARC 2012) This includes nickel compounds which IARC documents cause lung and nasal cavity and paranasal sinus cancer. (IARC100c-10, 2012). Nickel compounds "cause DNA damage, chromosomal aberrations, delayed mutagenicity and chromosomal instability … and nickel compounds act as co-mutagens." Talcum powder products also contain Chromium (VI) another Group 1 carcinogen (IARC100c 2012), where there is sufficient evidence in humans for carcinogenicity (to the nose and nasal sinus). The mechanism includes "DNA damage, generation of oxidative stress and aneuploidy. Talc powder products can also contain Group 2A metals that are considered probably carcinogenic to humans, such as Cobalt which can be found in talc powder products. (IARC 2006) IARC considers Cobalt metal with tungsten carbide as probably carcinogenic to humans (Group 2A), but worth noting that a number of the IARC working group members supported an evaluation in Group 1 because they judged the epidemiological evidence to be sufficient, leading to an overall evaluation in Group 1; or they judged the mechanistic evidence to be strong enough to justify upgrading the default evaluation from 2A to 1. The majority of working group members, who supported the group 2A evaluation, cited the need for either sufficient evidence in humans or strong mechanistic evidence in exposed humans. Cobalt metal without tungsten carbide is also considered possibly carcinogenic to humans (Group 2B). Cobalt sulfate and other soluble cobalt(II) salts are possibly carcinogenic to humans (Group 2B).

All of these heavy metals can cause ovarian cancer through an inflammatory mechanism.

Fragrances

There are more than 150 different chemicals added to Johnson's Baby Powder and Shower to Shower products. I reviewed the expert report from Dr. Crowley that concludes that some of these chemicals may contribute to the inflammatory response, toxicity, and potential carcinogenicity of Johnson & Johnson's talcum powder products. I concur with his opinion. (Crowley expert report 2018)

IV. Overview of Publications on Genital Use of Talc Powder Products and Ovarian Cancer

To understand the relationship between exposure to talcum powder products and ovarian cancer, I searched for and reviewed scientific papers on this topic. I used several searchable publication databases (Scopus, Embase, Pubmed, Cochrane etc.) and manually searched the reference lists of all articles I found, including a large number of reviews. I felt the existing reviews did not sufficiently address the risks associated with *frequent use* of talcum powder products. Therefore, I collaborated with colleagues at UCSF (several individuals not involved in talc related litigation including the lead author) to complete a quantitative systematic review focused on this question (see Woolen, **Systematic Review Registration:** PROSPERO CRD42020172720.)

Consideration of Research Study Design and Statistical Significance

There is a widely-held belief that there is a strict hierarchy of research study designs, where randomized trials are the most valid study type, followed by cohort studies and case controls studies being the least reliable.

(Rothman 2008) However, this is simply not true, as well described by Rothman in an article entitled "Six Persistent Research Misconceptions." (Rothman 2016) Rothman describes the fallacy of this belief. Each type of study design has both strengths and biases. Ascribing greater validity to one study design over another is both simplistic and fallacious. He specifically notes that case-control and cohort studies are conceptually identical, and that "a properly designed case control study can achieve the same excellent validity as a properly conducted cohort study."(Rothman 2016) I am not saying that all studies are identical in their validity, rather, that one cannot determine the validity based on the design chosen.

A second misconception is that the classification of study results into ''significant'' and ''non-significant'' based on statistical significance and a p-value is often arbitrary and leads to an invalid interpretation of data.(Greenland et al. 2016) It is more important to estimate the effect size and the uncertainty surrounding the estimate (with a point estimate and confidence interval) rather than using a significance level and p-value to determine if there is/or is not a meaningful association. There is no inherent or meaningful difference between a study with a p-value of 0.04 compared with 0.06, and yet these are often wrongly considered reflective of significant and non-significant results respectively. Similarly, a large effect size with a large p-value (i.e. non-significant) may reflect an insufficiently large sample size, but nonetheless an important association. As Rothman notes, "Significant tests are a poor classification scheme for study results; strong effects may be incorrectly interpreted as null [negative] findings because authors fallaciously interpreted the lack of statistical significance to imply lack of effect, or a weak effect may be incorrectly interpreted as important because they are statistically significant. Rather than be used as surrogate for significant tests, confidence intervals should be used as a quantitative measure indicating the magnitude of effect size and degree of precision with little attention paid to the precise location of the boundaries of the confidence interval.' (Rothman 2016) These considerations should be kept in mind when reading studies and assessing whether a large number of studies provide a consistent estimate of an effect size, ignoring the individual p-values of each study, and instead focusing on the effect size.

Explanation of study designs and article types reviewed

Nearly all published studies that I reviewed used one of two designs: case-control and cohort. Each design has strengths and biases. Many articles I reviewed were also systematic reviews, which are also explained.

Case-control studies compare people with a condition (cases) by matching them to people with similar characteristics who do not have the condition (controls) to determine the effect of a potential disease-causing factor. They often analyze existing data *retrospectively, after people have been diagnosed,* and involve tens or hundreds of patients. *Cohort studies compare cohorts, or groups of people, who were exposed or not exposed to a potential disease agent.* They often collect data on people *prospectively before they develop a disease* and track their health over time. Both case-control and cohort studies, if well done, can provide accurate and meaningful information about statistical associations. In general, however, the risk of bias is greater for case-control studies. An example is *recall bias*, in which women are more likely to remember and report exposure to talc powder products after they have been diagnosed with cancer compared to women without a diagnosis, perhaps because diagnosed women heard that talc powder products is harmful and are more likely to remember talc use. However, a recent study suggests self-reported use of feminine products is indeed likely reliable (O'Brien, 2023.) O'Brien and colleagues assessed the reliability of self-reported data. The authors collected retrospective data on douching and genital talc use in the US-based Sister Study at two-time points and evaluated the consistency of reporting. At enrollment (2003-2009), participants were asked to report use in the last year and during ages 10-13. On a follow-up questionnaire (2017-2019), participants were asked about their use of douche or genital talc over their lifetimes. Comparisons across the two questionnaires for use in the year before enrollment showed good consistency, with 90% providing the same responses about

douching and 87% providing the same responses about genital talc use. Reliability did not vary by cancer status, race, and ethnicity, attained education, or age, though there was some evidence of recall bias for genital talc use among ovarian cancer survivors. The authors concluded that ever use of feminine hygiene products may be recalled with good consistency. This supports the validity of the case-control design.

When studying a rare disease, the case-control design is frequently highly efficient and desirable as it allows you to assemble a much larger number of cases and can delve in great depth for particular exposures. You can identify all patients who have the outcome of interest, and then query them (and some control group) about any antecedent exposure. The identification of the control group is very important. As the PI on a large, National Institutes of Health-funded study of cancer risk factors in children we have employed a case-control design. This design permits us to ask very detailed questions of a small number of individuals about their various exposures.

Cohort studies potentially avoid some biases of case-control studies since exposures are prospectively assessed and quantified, that is, before disease outcomes. This design also has limitations, though. An important limitation is that because cohort studies are expensive and time-consuming, they rarely focus on a single, narrowly defined question such as the association between regular use of talcum powder products and cancer. Usually, researchers investigate a broad range of questions in cohort studies, so asking patients in-depth questions about any given topic is difficult, especially since tens of thousands of patients may be surveyed on many topics. Further, in cohort studies, having comprehensive assessment of outcomes on all individuals in the cohort is extremely important. Losing patients to follow up (meaning researchers cannot contact or find records on a participant) leads to study bias. The other disadvantage of cohort studies is that a very large number of patients must be assessed over a long period of time to see who will develop a rare outcome (like ovarian cancer). Because of this, typically there will be far fewer patients with disease in a cohort study as compared with case control study (like in this case).

There have been a small number of cohort studies that have explored the relationship between talcum powder products exposure and ovarian cancer and are described in depth below. While they all included questions about talcum powder exposure, all did not quantify the exposure in equal detail. Those that did assess more granular data provide more useful information. Interesting while some of the earlier publications of the cohorts had very short follow-up periods, later publications (including a recent publication by O'Brien) and data from the NHS (Woolen) include more cancers because of the longer period of follow up.

Systematic reviews quantitatively summarize results across multiple studies. One of the rationales of this study design is that individual studies may not have enough participants to yield meaningful or conclusive results because they are too small or insufficiently powered. Combining small studies can provide more stable and reliable summary estimates of the effects of disease agents and risk factors. Further, a systematic review may be better than a single study, as it provides broader evidence of the results and includes patients from diverse settings. However, in order to statistically combine and summarize the data from different research studies into a single systematic meta-analytic review, the combined studies must ask the same research question and follow sufficiently similar and rigorous scientific methods. A meta-analysis does not compensate for gaps or flaws in an original study: Combining three poorly performed studies does not yield reliable summary estimates even though there may be three times the number of patients. Similarly, combining studies that ask different research questions (for example, assessing women of different ages for a disease in which age is an important risk factor) does not provide reliable summaries. Results from different studies often vary when the studies ask different research questions, have different criteria for including participants, or use different

methods. I raise these issues to point out that systematic reviews must be read extremely carefully to ensure that their conclusions are valid.

Table of Reviewed Publications

I identified and reviewed 49 English-language publications that provided quantitative data based on epidemiological studies about the relationship between genital talcum powder exposure and ovarian cancer (Table 3). This list includes 4 cohort studies, 10 systematic meta-analytic reviews, 4 studies that pooled individual patient-level data from several research studies, and 30 case-control studies. One study contributed both the systematic review and a case control study. I also read many review articles that are not included in the table. The epidemiological studies were published between 1982 and 2022. I have described the results organized by study design below.

Most studies used a case-control study design with a small number using a cohort study design. Although some studies assessed powder use to any part of the body or assessed the use of talcum powder on diaphragms, condoms or sanitary napkins, the primary research question that I focused on in my review and that was assessed in all included individual research studies, was whether genital area exposure to talcum powder increases risk of epithelial ovarian cancer. Occasionally, study authors assessed combination exposures (i.e., to genitals and other body parts). These studies were included as long as genital powder use was assessed. Nearly all studies adjusted for known ovarian cancer risk factors, but those factors varied. The vast majority of studies found a positive association between any exposure to talcum powder products and cancer. However, the sample size of some studies was small and resulted in high statistical uncertainty. Because of these and other limitations, quantifying a precise association between exposure and cancer was difficult from my review of the literature. The data for some studies may have shown that effects of talcum powder exposure (measured as odds ratios, ORs) was meaningful for cancer development, but many had statistical uncertainty. I was also concerned about understanding “ever” exposure, versus “regular” exposure, and I thought a review focused on regular use would be helpful (see below).

A subset of the studies quantified the *intensity (frequency)* of each woman’s exposure to talc to assess the importance of use patterns (e.g., if a single lifetime use or weekly, monthly, or daily use increased ovarian cancer risk) or *dose dependency (links between the number of exposures and cancer risk, e.g., if doubling exposure doubles risk)*. Further, a subset of studies stratified by cancer type (invasive vs. low malignant potential/borderline) and whether the risks varied by histological types including the four dominant types of serous, mucinous, clear cell, and endometrioid cancer.

Studies that provided data on the frequency of talc use and association by histologic type were included in a recent review, Woolen et al. 2022.

Quantifying Exposures

A large proportion of women will have used talcum powder products, highlighting the importance of this issue. However, publications that focus on women reporting “any“ genital exposure to talc (i.e., talc at any point in life and for any duration) may be too broad to provide meaningful information. For example, “any use” will include women who applied talc powder products three times over five decades and women who used talc powder products daily, whose might have had 20,000 applications and exposures in comparison to three. Defining a variable as any use is the equivalent to creating a variable of any smoking use, that combines data on individuals who tried one cigarette in their life with individuals with 50 pack years of tobacco use. Combining data on women with infrequent or sporadic exposures with data from women with frequent, sustained use leads to imprecise results, masking any causal associations. Woolen et al limited their review to

studies that quantified the frequency of talc powder products as these studies contained the most informative data.

Summary of Data
I grouped the research studies below by their study design, Table 3. What follows is my review of the cohort studies, quantitative systematic review studies, and pooled data studies.

Cohort Studies
Four cohorts (The US Nurses' Health Study I, The US Nurses' Health Study II, The Women's Health Initiative and the Sister Study) have been utilized to study the relationship between the use of talcum powder products and ovarian cancer, and the five publications from these cohort studies are described below. O'Brien and colleagues performed a pooled analysis of genital powder use and ovarian cancer using data from the four cohort studies which is discussed below under pooled data studies.

Gertig (2000)
This first cohort study assessed the relationship between perineal talc and ovarian cancer within the context of the US Nurses' Health Study, a prospective study of 121,700 female registered nurses in the United States who were aged 30–55 years at enrollment in 1976. These are mostly premenopausal women. While talc exposure was not an initial part of the study, questions about talc, including measuring frequency of exposure, were added in 1982; a large subset of the cohort (78,630 women) completed these questions and were included in analyses. Among these women who were followed for 14 years, 307 were diagnosed with epithelial ovarian cancer. After adjusting for confounding variables, the *relative risk (RR)* of developing ovarian cancer (*the likelihood of ovarian cancer in talc users compared to nonusers, with higher RR meaning increased risk stronger association*) among daily users of talc was RR 1.12 (95% *confidence interval [CI]* 0.82, 1.55, *a measure of statistical uncertainty, with wider ranges indicating greater uncertainty*), which was not statistically significant. However, when results were classified by histologic subtype, the RR of invasive serous cancers was significantly elevated among any users of talc (RR 1.40, 95% CI 1.02, 1.9) and the RR of invasive serous cancer among daily users of talc was higher at RR 1.49 (95% CI 0.98, 2.3).

In this cohort study, the researchers assessed talc exposure before cancer diagnosis, avoiding the possibility of the recall bias of case-control studies. This was a strong strength of this study. A potential weakness was that frequency (i.e., daily) but not duration (number of years) of talc use was measured, so a clear lifetime exposure measure was missing. The researchers nonetheless quantified exposure at the time the talc questions were asked, which was probably strongly associated with prior use (i.e., an approximation on ongoing use). **This study provides strong evidence that perineal exposure to talc increases the risk of invasive serous ovarian cancer, particularly among daily users of talc, with about a 50% increased risk**, which is substantial and meaningful.

Gates (2010)
This study assessed the association between ovarian cancer risk factors and incidence of ovarian tumors by histological type using data from the US Nurses' Health Study combined with data from the Nurses' Health Study II, which included a second period of enrolling participants. Unfortunately, talc use was assessed only on the first survey and not assessed among patients enrolled in the Nurses' Health Study II. Thus, this extends the period of follow up from the initial NHS but does not include greater information about risk factors. Results were presented for any talc powder products use and not for frequency of use. **Thus, this report does not add to a meaningful assessment of the relationship between talc use and ovarian cancer because it used exactly the same patient group as Gertig (2000) but provided less information to quantify the frequency of talc use.**

Woolen et al. completed a systematic review in 2022 focused on summarizing publications that report on women who reported frequent genital talcum powder use, described in more detail below in the section analyzing systematic reviews. As part of that effort, Woolen was able to obtain and report previously unpublished follow up data from The Nurses' Health Study I cohort that describe women who reported frequent, approximately daily talc exposure (the same group as described above under Gertig but with a longer period of follow up). These results are highly relevant as they provide the most comprehensive follow up data to the largest cohort study where frequent talcum powder use was assessed. In the pooled analysis of the four cohorts, O'Brien et al did not include these data from the NHS I cohort on frequent talc users, but instead focused primarily on any use of talc in the NHS I cohort.

Detailed data of these long term follow up results from the NHS I cohort are included in the Supplemental tables of the Woolen systematic review and are included in the table below (Supplemental table 1 from Woolen). Data were included from the highest reported talc use category to obtain as close to daily use as possible and the referent group were women who reported no talc exposure. In summary, among all women who reported frequent talcum powder use, the adjusted Hazard Ratio is a significant 1.27 (95% CI 1.09, 1.49) and among all women who reported frequent talcum powder use with patent fallopian tubes, the adjusted Hazard Ratio is a significant 1.40 [95% CI 1.17, 1.68]

Supplementary Table 1 from Woolen. Hazard Ratios and 95% Confidence Intervals for the Association between Frequency of Genital Powder Use and Risk of Ovarian Cancer in the Nurses' Health Study

	Person-time at risk[a]	Non-cases[a]	Ovarian cancer cases[a]	Crude Hazard Ratio (95% CI)	Adjusted Hazard Ratio[b] (95% CI)
All women					
Non-users	1,263,610	46,786	706	1.00	1.00
Less frequent users	566,785	20,979	302	0.96 (0.84, 1.09)	0.96 (0.84, 1.10)
Daily users	300,402	11,290	216	1.27 (1.09, 1.48)	1.27 (1.09, 1.49)
Women with Patent Fallopian Tubes					
Non-users	838,445	31,040	475	1.00	1.00
Less frequent users	373,969	13,796	218	1.03 (0.88, 1.21)	1.04 (0.88, 1.68)
Daily users	196,578	7,355	157	1.40 (1.17, 1.67)	1.40 (1.17, 1.68)

[a]*Among participants with complete covariate information. Includes all self-reported cases.*
[b]*Hazard ratios are adjusted for race/ethnicity (white, black, other), education ≤high school, some college, ≥college graduate), BMI (as a restricted cubic spline), parity (0, 1, 2, 3+ births), ever oral contraceptive use, tubal ligation (yes/no), hysterectomy status (yes/no), menopausal status (pre or post-menopausal), ever hormone therapy use. All covariates correspond to status at time of genital powder assessment.*
[f]Patency defined as having a uterus (i.e. no hysterectomy) and not having had a tubal ligation

Houghton (2014)

This study assessed perineal talc powder products use and risk of ovarian cancer in the Women's Health Initiative Observational study, in which postmenopausal women aged 50–79 were enrolled in a prospective cohort of women from 40 clinical centers across the United States in 1993–1998. Overall, 61,576 women were included in analyses, including 429 diagnosed with ovarian cancer. Perineal powder use was assessed at the start of the study. Participants were asked if they **ever used talc powder products** on their private parts (genital areas). Those who responded yes were asked about duration (years) of use. Women were followed for a mean of 12 years and the median age of participants was 63. **Talc powder products use was associated with a 12% increase in risk of ovarian cancer after accounting for covariates** (RR 1.12, 95% CI 0.92, 1.36). When limited to women who used perineal powder for 20 years or more, the RR was 1.10 (95% CI 0.82, 1.48). When limited to serous ovarian cancer, the RR was 1.13 (95% CI 0.84, 1.51.) **The primary limitation of the study was**

that frequency of talc powder products use was not assessed—and thus the authors could focus only on any talcum powder use. The imprecision in estimation of talcum powder exposure makes the results not terribly meaningful. The second and extremely important limitation was the relatively short follow-up of 12 years to identify ovarian cancer diagnoses.

Gonzalez (2016)

The Sister Study (2003–2009) followed 50,884 women ages 35 to 75 years in the US and Puerto Rico who had a sister diagnosed with breast cancer. After excluding participants who had bilateral oophorectomies, ovarian cancer, or were lost to follow-up, 41,654 participants were included. At baseline participants were asked about douching and talc use during the previous 12 months, and during follow-up (median of 6.6 years) 154 participants reported a diagnosis of ovarian cancer. The authors computed adjusted hazard ratios (HR) and 95% confidence intervals (CI) for ovarian cancer risk using the Cox proportional hazards model. The authors found no significant association between baseline perineal talc use and subsequent ovarian cancer (HR: 0.73 CI: 0.44, 1.2). **The primary limitations of this study are that the authors combined a large number of potential talc exposures into a single category, including genital talc use in the form of powder or spray applied to a sanitary napkin, underwear, diaphragm, cervical cap, or vaginal area. Further, the authors categorized the exposure based on the 12 months prior to enrollment as a dichotomous ever/never.** Thus not only was it an ever versus never category, the ever category was extremely broad, making the lack of association less meaningful. Further, there are several other factors that make the results questionable, including the lower than expected proportion of women who report any exposure to talc powder products, and the lack of a validated approach to ascertainment of ovarian cancer.

O'Brien (2024)

The Sister Study (described in the previous paragraph) has been recently updated with re-evaluation of the association between talcum powder use and ovarian cancer among the Sister cohort (the publication also assessed other cancers that will not be addressed here.) This expands on the previous analysis in two important ways by 1) incorporating results of a fourth follow up questionnaire conducted in 2017-2019 that asked more detailed and granular questions about lifetime genital talcum powder use, and 2) the inclusion of newly diagnosed ovarian cancers through a longer period of follow up through September 2021 during which a larger number of additional ovarian cancer cases could accrue (see screen shot from publication below). These are very important updates. Whereas the initial report described 154 cases of ovarian cancer, the longer period of follow up of the cohort includes 292 cases, nearly twice as many ovarian cancer cases. Further, while the initial report describes an improbably low exposure of 14%, the updated analyses reflect exposure estimates of 35% - 56%, which are consistent with other sources of talcum powder exposure data. The authors primarily focused on ever versus never use but also considered frequency, duration, and timing of use.

Because women were surveyed during two very disparate periods of time, and because the newly acquired exposure data were susceptible to differential missingness by cancer status, the authors assessed the classification of women's exposure when either the reporting of their exposure differed between surveys or when women did not complete the second survey. The authors used quantitative bias analysis to estimate effects under several missingness assumptions and to predict the impact of errors in recall. In short, the broad approach the authors used to reconcile the inconsistencies with misclassification of exposures and missing data on exposures was to essentially estimate the extremes of possibility where the truth would lie somewhere between the extremes. For example, the authors estimated the impact if all women with missing exposure data on the follow up were non-exposed versus if all women with missing exposure data on the second follow up were exposed, and these extremes would demonstrate the range of possible results defined

by how women in the undefined category are classified. The true value of the exposure distribution would fall somewhere within this range and between the two extremes. Further, the authors used established techniques of multiple imputation to generate covariate-informed probabilistic imputations of the exposure status of participants who were undefined or missing. Lastly the authors accounted for potential bias in reporting of women on their exposures. To address this issue of misclassification of exposure, O'Brien et al considered a range of possible exposure misclassifications by both the cases and the controls and recalculated the results to show that even with a fairly large degree of exposure misclassification, the association between genital use of talcum powder products and ovarian cancer persists.

As noted by Harris et al in the accompanying editorial, comments with which I strongly agree, "[a]fter accounting for potential biases, O'Brien et al report a significant increase in ovarian cancer risk for genital powder use, with effect estimates that are in range with previous studies. The association is the strongest for genital powder exposure during the age ranges of 20s and 30s. . . ." Harris further goes on to note that even if there was "misreporting of the exposure [of genital powder use] in half of the cases [an extreme rate of misreporting], a significant increase in ovarian cancer risk is still observed, adding support to the plausibility of a true association between genital powder use and ovarian cancer risk."

For example, in the models adjusted for exposure misclassification, genital talc use was positively associated with ovarian cancer (HR range, 1.17-3.34), with higher rates seen for frequent and long-term users. Using recall bias corrected hazard ratios, the association between genital talc use and ovarian cancer was higher for frequent users (HR 1.81 [95% CI, 1.29 to 2.53]) and long-term users (HR 2.01 [95% CI, 1.39 to 2.91]), compared with never users (P for trend .001.) The results for frequent users were consistent with Woolen (2022). Analyses jointly considering patency and genital talc use relative to never use, showed a potentially stronger association with ovarian cancer among women who used while patent (HR, 1.55 [95% CI, 1.14 to 2.09]). Associations between genital talc use and ovarian cancer remained positive, though attenuated, in most plausible bias corrected quantitative bias analyses addressing missing data biases and potential differential reporting of genital talc use by ovarian cancer status. These findings strongly support that there is a positive association between genital talc use and development of ovarian cancer.

The predictive modeling and sensitivity analyses that were performed were extensive, thoughtful and consistent with well accepted methodology and provide compelling evidence that in this large cohort study, now with better exposure assessment and longer follow up, exposure to talcum powder products is associated with ovarian cancer.

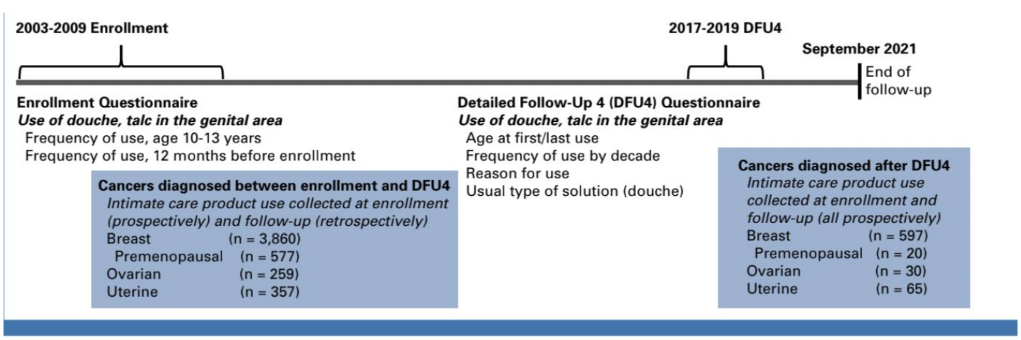


FIG 1. (A) Flowchart and (B) timeline describing characteristics and questionnaire data from Sister Study participants included in the quantitative bias analysis of intimate care product use and incidence of female hormone–related cancers.

Cohort Studies: Summary

Analyses of data from the US Nurses' Health study (including the longer years of follow up) and from the recently updated results from the Sister Study (also with a longer period of follow up combined with updated

exposure assessment) strongly support that genital exposure to talcum powder significantly increases the risk of ovarian cancer. These results are consistent. While the WHI study does not demonstrate a statistically significant association, the short period of follow up and limited exposure information, as described above, are acknowledged limitations and would tend to bias the results toward the null.

Systematic Reviews

Ten systematic reviews, and a single systematic review of systematic reviews, that quantitatively summarized the relationship between talc and ovarian cancer, are summarized below. These reviews were completed using various subsets of the full list of publications. The reviews are presented with the most recent first, because the more recent studies tended to be more complete, comprehensive and the most methodologically rigorous.

Woolen (2022)

Woolen et al. completed a systematic and quantitative meta-analytic review of the relationship between regular use of talcum powder products and ovarian cancer. This research was motivated by my earlier work reviewing the talcum powder literature, as I identified a gap in evidence focused on women who used talcum powder products regularly. I was a collaborator on this research, but the lead first author researcher and the biostatistician were not involved in the talc litigation in anyway. As noted by the authors, "A systematic review and meta-analysis was conducted according to meta-analysis of observational studies in epidemiology guidelines. The study protocol was prospectively registered at PROSPERO (registration number CRD42020172720). Searches were performed in PubMed, Embase, Web of Science, and Cochrane Central Register of Controlled Trials databases from their inception to August 2, 2021. Case-control and cohort studies were included if they reported frequent perineal talcum powder use and an adjusted odds ratio or hazard ratio for ovarian cancer. Review for inclusion, data extraction, and quality assessment (using the Newcastle-Ottawa Scale [NOS]) were performed independently by two reviewers. Pooled adjusted odds ratios with 95% confidence intervals were generated from the random effects model. Heterogeneity was quantified with I^2 statistic. Funnel plot and Eger's test were performed to assess publication bias. Subgroup and sensitivity analyses were performed for testing the robustness of the overall findings."

"The Initial database searches returned 761 unique citations and after review, eleven studies describing 66,876 patients, and 6542 cancers were included (Cohen's κ = 0.88). Publication quality was high (median NOS = 8, range: 4 to 9). Frequent talcum powder use was associated with an elevated risk of ovarian cancer (adjusted pooled summary odds ratio 1.47 (95% CI 1.31, 1.65, P<0.0001). There was no evidence of bias and low heterogeneity (I^2= 24%, P=0.22). There was no meaningful difference limiting analysis to publications with a NOS quality score of 8 or 9 or limiting studies based on study design." This review suggests an increased risk of ovarian cancer associated with frequent perineal powder exposure of 31-65%.

Taher (2019)

This is a comprehensive systematic review of the association between any perineal use of talcum powder products and ovarian cancer. The authors identified 30 studies (4 cohort and 26 case control studies), and a subset of 27 were included in their analysis as having reported between ever use of perineal talc and ovarian cancer. They found a positive association between any perineal use of talc powder products and ovarian cancer (OR 1.28 [95% CI 1.20, 1.37.]) They also performed several subgroup analysis, focusing on frequency and duration of use, tumor histology, type of use, period of use and menopausal status. They also analyzed by the quality assessment of the study (they found no association). The notable subgroup analyses showed greater risk with high frequency of talc use, reflecting approximately daily use (OR 1.39 [95% CI 1.22, 1.58]), elevated risks for Serous cancer (OR 1.38 [95% CI 1.22, 1.56]) and Endometrioid cancer (OR 1.39 [95% CI 1.05,

1.82]) and that certain patient groups had higher risk (for example, among post menopausal women using hormone replacement the OR was 2.28 [95% Ci 1.72, 3.01]). They found the results of the different studies were inconsistent with respect to identifying a dose response, but identified a possible trend with increasing ovarian cancer risk with increasing cumulative (lifetime) exposure – noting however that there was heterogeneity among studies. They also described animal studies which supportive oxidative stress, immune system alterations and inflammatory responses as being possible mechanisms for cancer development.

Penninkilampi (2018)
This comprehensive systematic review of the association between any genital use of talcum powder products and ovarian cancer conducted a stratified analyses showing the association by frequency of talc use and histologic cancer subtype. The methods of the study are well described. The researchers identified studies using six electronic databases and reviewed publications with 50 or more cases of ovarian cancer. They identified 24 case-control studies describing 13,421 cases and the three cohort studies (890 cases, 181,860 person-years) described above. Any reported use of perineal talc powder products was associated with increased risk of ovarian cancer compared to no use (OR = 1.31; 95% CI 1.24, 1.39). Women with more than 3600 lifetime applications had slightly higher risks (OR = 1.42; 95% CI 1.25, 1.61). Women who reported long-term (>10 years) talc use also had an increased risk (OR 1.25; 95% CI = 1.10, 1.43). The association between any talcum powder product exposure and ovarian cancer was limited to studies that used a case-control design.

The cohort studies showed an increased risk of serous invasive cancer subtypes for perineal talc use compared to no use (OR = 1.25; 95% CI = 1.01, 1.55). While serous and endometrioid cancer were associated with talcum powder products use, no association was seen with mucinous or clear cell cancers. The review authors concluded, from the data, that perineal talcum powder use and ovarian cancer were consistently associated, with a slightly higher risk in women who report greater usage. Some variation in the magnitude of the effect of talcum powder products was found when considering the study designs and ovarian cancer subtypes. Several minor issues are that Penninkilampi may have included some groups of patients more than once in analyses and did not include updated data or previously unpublished data available from a research consortium on ovarian cancer. However, these concerns are unlikely to have had a significant impact on estimates.

Berge (2018)
This large, comprehensive systematic review of the association between genital use of talc powder products and ovarian cancer also had well-described methods. Berge reviewed and abstracted data for 27 publications and reported an overall summary estimate of the association between talc exposure and ovarian cancer. For six of the reviewed studies, Berge included data published in a pooled data analysis, from Terry [69] described below) that had not been previously included in the original publications. Overall, data on 15,230 women with ovarian cancer were analyzed (a number that is incorrectly reported in the paper). This is slightly higher than the number included in Penninkilampi because of the additional patients from the Terry publication. The summary estimate for risk of ovarian cancer for women who ever used genital talc was RR 1.22 (95% CI 1.13, 1.30). When stratified by histologic type, serous carcinoma was the only type with a significant association to talc use (RR 1.24, 95% CI 1.15, 1.34). There was no difference in risk when tumors were categorized as invasive versus borderline.

To assess relationships among ovarian cancer and intensity and duration of use, these measures were analyzed separately rather than as a combined measure that would give an estimate of the total number of exposures. Nonetheless, the authors found statistically significant relationships with both frequency and duration of use: " The results of the analysis by duration and frequency of genital talc use are reported in

Table 3. A 10-year increase in genital talc use was associated with a RR of 1.16 (95% CI 1.07-1.26; 12 studies), whereas the RR for an increase of one application per week was 1.05 (95% CI 1.04-1.07; 7 studies). " This means that per each additional application per week the relative risk of cancer increased 5 percent, meaning that frequent and daily use would be associated with approximately a 35% increase in cancer risk (RR aproximately 1.35.)

The authors also stratified the results by the study design (as did Penninkilampi) and found that the association between talc exposure and ovarian cancer was significant only for the case-control studies, although, as above, the cohort studies had the weakest definition of exposure. The primary limitation of the review is defining exposure as ever having used talc. As described above, this is a broad, vague definition that probably dilutes any estimated association, as it includes both women with trivial use and with regular use. A second limitation is that the included studies adjusted for a variety of covariates although this is unavoidable in this type of summary. The large difference in general between adjusted and crude results emphasizes the importance of adjustments when estimating particular risk.

Langseth (2008)

This systematic review of the association between genital use of talc powder products and ovarian cancer included 21 publications. The overall pooled odds of cancer were OR 1.35 across all studies. Several authors of this systematic review were involved in an IARC report on talc exposure. They analyzed a subset of eight studies used in the IARC report that were considered to be the most informative for estimating ovarian cancer risk. Analysis of these more relevant, higher quality studies, produced an increased ovarian cancer risk of 30 to 60% (presumably OR 1.3–1.6) associated with talcum powder use. This subset analysis did not document a dose response or assess associations by cancer types.

Huncharek (2007)

Huncharek summarized the results of nine studies that reported on the association between talc used on contraceptive diaphragms and ovarian cancer. No data on perineal talc exposure were analyzed and the data are not included herein. Of note, the reported methodological details suggest a very poorly designed and conducted study. Some of the included papers do not even mention talcum powder products used with diaphragms. This systematic review is poor quality.

IARC (2010)

Beginning in 1969 the International Agency for Research on Cancer (IARC) began a program to critically review the data on the carcinogenic risk of chemicals to humans. They subsequently expanded their reviews to included evaluation of carcinogenic risks associated with a range of exposures (including risks associated with biological and physical agents, lifestyle factors, complex mixtures of exposures, occupations, etc.) The purpose of the IARC program is to elaborate and publish detailed monographs including critical review of data, to evaluate human risks, and to indicate where uncertainty exists and where additional data are needed. They also give an overall assessment of the strength of the associations. It is worth noting that the individuals who contribute to IARC reports (the Working Group) include extremely knowledgeable and unbiased scientists who have specific content expertise and who have no apparent conflicts of interest. Invited specialists and representatives from international health agencies are brought in to supplement the scientific experts. In their evaluation, they heavily weight whether data support a conclusion of causality. They score evidenced into four categories, ranging from a) evidenced suggesting lack of carcinogenicity; b) inadequate evidence of carcinogenicity c) limited evidence of carcinogenicity and d) sufficient evidence of carcinogenicity. Category c is used when there is possibly carcinogenicity, and this category is not used lightly. An exposure meets category c if there is a positive association between observed exposure to the agent and cancer for which a

causal interpretation is considered by the Working Group to be credible, but chance of bias or confounding could not be ruled out. They further categorize agents into 3 groups: Group 1, corresponding to d above (sufficient evidence), the agent is carcinogenic to humans; Group 2, which includes 2A (the agent is probably carcinogenic) and 2B: the agent is possibly carcinogenic to humans. A review focused on the risks associated with carbon black, titanium oxide and talc was published in 2006. The review included a detailed review of the individual studies examining perineal talc use as a risk factor for cancer. IARC concluded that perineal use of talc-based body powder is possibly carcinogenic to humans (Group 2B)

Huncharek (2003)
This review of 16 studies assessed the relationship between genital exposure to talc and ovarian cancer using data for 5260 women with cancer and 6673 controls. The pooled OR for ever being exposed to perineal talc powder products was 1.33 (95% CI 1.16, 1.45). Small differences were observed in the estimated ORs by whether controls in the case-control studies were from hospital populations (OR 1.19, 95% CI 0.99, 1.4), or the general population (OR 1.38, 95% CI 1.25, 1.52). I believe these differences are small. In general, in case-control studies, population controls are likely more relevant and valid. However, as with several of the other reviews, talcum powder exposure was assessed as any exposure rather than quantifying by intensity. No stratification by tumor subtype or invasiveness was performed.

Gross (1995)
Gross reviewed 10 studies on the association between talc exposure and ovarian cancer using data on 1333 women with cancer and 2362 without cancer. To summarize the RR of malignant epithelial cancer types due to any exposure to talc, adjusting for ovarian cancer risk factors, the authors combined results from five studies for OR 1.29 (95% CI 1.02, 1.63). For an analysis of all cancers (borderline and invasive), they included data from seven studies for a similar OR of 1.31 (95% CI 1.08, 1.58). Notably, the authors did not provide any methodological details of how they identified, assessed, and combined studies, making the results difficult to fully interpret. As with several of the other reviews, they assessed any exposure to talc.

Harlow (1992)
Harlow reviewed five previously published studies and summarized an OR, not adjusted for confounding factors, and added his own data for a crude estimated OR of 1.3 (95% CI 1.1, 1.6). Unfortunately, no methodological details were provided on how studies were identified, assessed, and combined or how exposure was defined, making the results difficult to fully interpret. Further, only the combined, estimated, non-adjusted crude OR was reported. Of note, the results of the five published studies used in the review (in contrast to the summary) are well described and of good methodological quality.

Tanha (2021)
Tanha and colleagues completed a large review of systematic reviews to identify and quantify the most important factors associated with ovarian cancer found in systematic reviews "A comprehensive systematic literature search was performed to identify all published systematic reviews and meta-analysis on associated factors with ovarian cancer. Web of Science, Cochrane Library databases, and Google Scholar were searched up to 17th January 2020. This study was performed according to Smith et al. methodology for conducting a systematic review of systematic reviews. Twenty-eight thousand sixty-two papers were initially retrieved from the electronic databases, among which 20,104 studies were screened. Two hundred seventy-seven articles met the inclusion criteria." The authors found that perineal talc use, significantly increase the risk of ovarian cancer, and the excess risk was greater than nearly all other assessed ovarian cancer risk factors. They report a summarized OR = 1.30 (95% CI 1.24, 1.36) and RR = 1.25 (95% CI 1.18, 1.33).

Table 3. List of published studies, sorted by study design

	Study Type	Year	Author	Journal	Title
1	Cohort	2000	Gertig	J Natl Cancer Inst	Prospective study of talc use and ovarian cancer (in the Nurses' Health Study)
2	Cohort	2010	Gates	Am J Epidemiol	Risk factors for epithelial ovarian cancer by histologic type; US Nurses Health Study
3	Cohort	2014	Houghton	J Natl Cancer Inst	Perineal powder use and risk of ovarian cancer: Results from the Women's Health Initiative
4	Cohort	2016	Gonzalez	Epidemiology	Douching, talc use and risk of ovarian cancer: Results from the Sister Study
5	Cohort	2024	O'Brien	J Clinical Oncology	Intimate Care Products and Incidence of Hormone-Related Cancers: A Quantitative Bias Analysis
6	Systematic Rev.	1992	Harlow	Obst Gyn	Perineal exposure to talc and ovarian cancer risk
7	Systematic Rev.	1995	Gross	J Expo Anal Env Epid	A meta-analytical approach examining the potential relationship between talc exposure and ovarian cancer
8	Systematic Rev.	2003	Huncharek	Anticancer Res	Perineal application of cosmetic talc and risk of invasive epithelial ovarian cancer: a meta-analysis of 11,933 subjects from sixteen observational studies
9	Systematic Rev.	2007	Huncharek	Eur J Cancer Prev	Use of cosmetic talc on contraceptive diaphragms and risk of ovarian cancer: a meta-analys of nine observational studies.
10	Systematic Rev.	2008	Langseth	J Epid Community Health	Perineal use of talc and risk of ovarian cancer.
11	Systematic Rev.	2010	IARC	IARC Monographs	IARC monographs on the evaluation of carcinogenic risks to humans: Carbon black, titaniur dioxide, and talc
12	Systematic Rev.	2017	Berg	European J of Can Prev	Genital use of talc and risk of ovarian cancer: A meta-analysis
13	Systematic Rev.	2018	Penninkilampi	Epidemiology	Perineal talc use and ovarian cancer: A systematic review and meta-analysis.
14	Systematic Rev.	2019	Taher	Reproductive Toxicology	Critical review of the association between perineal use of talcum powder and risk of ovariar cancer
15	Systematic Rev	2021	Tanha	J Ovarian Ca Research	Investigation on factors associated with ovarian cancer: an umbrella review of systematic review and meta-analyses
16	Systematic Rev.	2022	Woolen	J of General Int Medicine	Association Between the Frequent Use of Perineal Talcum Powder Products and Ovarian Cancer: a Systematic Review and Meta-analysis
17	Pooled Data	2013	Terry	Cancer Prev Res	Genital powder use and risk of ovarian cancer: a pooled analysis of 8525 cases and 9859 controls
18	Pooled Data	2016	Cramer	Epidemiology	The association between talc use and ovarian cancer- A retrospective case- control study in two US states
19	Pooled Data	2020	O'Brien	JAMA	Association of Powder Use in the Genital Area with Risk of Ovarian Cancer
20	Pooled Data	2021	Davis	Cancer Epid Biomark Prev	Genital Powder Use and Risk of Epithelial Ovarian Cancer in the Ovarian Cancer in Women of African Ancestry Consortium
21	Case-Control	1982	Cramer	Cancer	Ovarian cancer and talc: A case control study
22	Case-Control	1983	Hartge	JAMA	Talc and ovarian cancer
23	Case-Control	1988	Whittemore	Am J Epidemiol	Personal and environmental characteristics related to epithelial ovarian cancer. Exposures t talcum powder, tobacco, alcohol, and coffee
24	Case-Control	1989	Harlow	Am J Epidemiol	A case-control study of borderline ovarian tumors: The influence of perineal exposure to tal
25	Case-Control	1989	Booth	BR Cancer	Risk factors for ovarian cancer: a case-control study
6	Case-Control	1992	Harlow	Obstet Gynecol	Perineal exposure to talc and ovarian cancer risk
26	Case-Control	1992	Rosenblatt	Gynecol Oncol	Mineral fiber exposure and the development of ovarian cancer
27	Case-Control	1992	Chen	Int J Epidemiol	Risk factors for epithelial ovarian cancer in Beijing, China
28	Case-Control	1993	Tzonous	Int J Cancer	Hair dyes, analgesics, tranquilizers, and perineal talc application as risk factors for ovarian cancer
29	Case-Control	1995	Purdie	Int J Cancer	Reproductive and other factors and risk of epithelial ovarian cancer: an Australian case-control study
30	Case-Control	1996	Shushan	Fertil Steril	Human menopausal gonadotropin and the risk of epithelial ovarian cancer
31	Case-Control	1997	Chang	Cancer	Perineal talc exposure and risk of ovarian carcinoma
32	Case-Control	1997	Cook	Am J Epidemiol	Perineal powder exposure and the risk of ovarian cancer
33	Case-Control	1998	Green	In J Cancer	Tubal sterilization, hysterectomy and decreased risk of ovarian cancer.
34	Case-Control	1998	Godard	Am J Obstet Gynecol	Risk factors for familial and sporadic ovarian cancer among French Canadians: A case-contro study
35	Case-Control	1999	Cramer	International J of Cancer	Genital talc exposure and risk of ovarian cancer
36	Case-Control	1999	Wong	Obstet Gynecol	Perineal talc exposure and subsequent epithelial ovarian cancer: A case-control study
37	Case-Control	2000	Ness	Epidemiol	Factors related to inflammation of the ovarian epithelium and risk of ovarian cancer
38	Case-Control	2004	Pike	Fertil Steril	Hormonal factors and the risk of invasive ovarian cancer: A population based case control study
39	Case-Control	2004	Mills	Am J Epidemiol	Perineal talc exposure and epithelial ovarian cancer risk in the Central Valley of California
40	Case-Control	2008	Goodman	Endcor Relat Cancer	Association of two common single-nucleotide polymorphisms in the CYP19A1 locus and ovarian cancer risk
41	Case-Control	2008	Gates	Cancer Epid Bio Prev	Talc use, variants of the GSTM1, GSTT1, and NAT2 genes, and risk of epithelial ovarian canc
42	Case-Control	2008	Merritt	Int J Cancer	Talcum powder, chronic pelvic inflammation and NSAIDs in relation to risk of epithelial ovarian cancer
43	Case-Control	2009	Moorman	Am J Epidemiol	Ovarian cancer risk factors in African-American and white women
44	Case-Control	2009	Wu	Int J Cancer	Markers of inflammation and risk of ovarian cancer in Los Angeles County
45	Case-Control	2011	Rosenblatt	Gynecol Oncol	Mineral fiber exposure and the development of ovarian cancer
46	Case-Control	2012	Lo-Cignaic	Epidemiol	Aspirin, non-aspirin non-steroidal anti-inflammatory drugs, or acetaminophen and risk of ovarian cancer
47	Case-Control	2012	Kurta	Cancer Epid Bio Prev	Use of fertility drugs and risk of ovarian cancer: results from a U.S.-based case-control study
48	Case-Control	2015	Wu	Cancer Epid Bio Prev	African Americans and Hispanics remain at lower risk of ovarian cancer than non-Hispanic whites after considering nongenetic risk factors and oophorectomy rates
49	Case-Control	2016	Schildkraut	Cancer Epid Bio Prev	Association between body powder use and ovarian cancer: the African American Cancer

Table 4. List of published studies Including the number of cancers and controls/cohort size.

	Study Type	Year	Author	Cancers	Controls or Cohort Size
1	Cohort Study	2000	Gertig	307	78,630
2	Cohort Study	2010	Gates	797	108,073
3	Cohort Study	2014	Houghton	427	61,576
4	Cohort Study	2016	Gonzalez	154	41,654
5	Cohort Study	2024	O'Brien	292	40,536
6	Systematic Review	1992	Harlow *	1,106	1,756
7	Systematic Review	1995	Gross	1,333	2,362
8	Systematic Review	2007	Huncharek	1,858	2,830
9	Systematic Review	2003	Huncharek	5,260	6,673
10	Systematic Review	2008	Langseth	NR	NR
11	Systematic Review	2010	IARC	NR	NR
12	Systematic Review	2017	Berg	15,230	NR
13	Systematic Review	2018	Penninkilampi	14,311	NR
14	Systematic Review	2019	Taher	17301	NR
15	Systematic Review	2013	Tanha	50,028	218166
16	Systematic Review	2016	Woolen	6,542	66,876
17	Pooled Data	2013	Terry	4,472	6,175
18	Pooled Data	2016	Cramer	2,041	2,100
19	Pooled data	2020	O'Brien	2.168	252,745
20	Pooled Data	2021	Davis	3420	7881
21	Case-Control	1982	Cramer	215	215
22	Case-Control Study	1983	Hartge	135	171
23	Case-Control Study	1988	Whittemore	188	539
24	Case-Control Study	1989	Harlow	116	158
25	Case-Control Study	1989	Booth	235	451
6	Case-Control Study	1992	Harlow	235	239
26	Case-Control Study	1992	Rosenblatt	77	46
27	Case-Control Study	1992	Chen	112	224
28	Case-Control Study	1993	Tzonous	189	200
29	Case-Control Study	1995	Purdie	824	860
30	Case-Control Study	1996	Shushan **	200	408
31	Case-Control Study	1997	Chang	367	564
32	Case-Control Study	1997	Cook	313	422
33	Case-Control Study	1998	Green	824	855
34	Case-Control Study	1998	Godard	170	170
35	Case-Control Study	1999	Cramer	563	523
36	Case-Control Study	1999	Wong***	499	755
37	Case-Control Study	2000	Ness	767	1,367
38	Case-Control Study	2004	Pike	NA	NA
39	Case-Control Study	2004	Mills	256	1,122
40	Case-Control Study	2008	Goodman	367	602
41	Case-Control Study	2008	Gates	NA	NA
42	Case-Control Study	2008	Merritt	1,576	1,509
43	Case-Control Study	2009	Moorman	1,086	1,057
44	Case-Control Study	2009	Wu	609	688
45	Case-Control Study	2011	Rosenblatt	812	1,313
46	Case-Control Study	2012	Lo-Cignaic	902	1,802
47	Case-Control Study	2012	Kurta	902	1,802
48	Case-Control Study	2015	Wu	1,701	2,391
49	Case-Control Study	2016	Schildkraut	584	745

Systematic Reviews: Summary

The systematic reviews provide a remarkably consistent estimate of an approximately 30% increase in the risk of ovarian cancer associated with any talc powder products use, with up to a 65% increase among frequent users of talc powder products. The studies summarized in the systematic reviews reported consistent results with little variability and closely overlapping estimates for ovarian cancer risk due to talc use. Further, the reviews suggest that the risks are greater for invasive serous cancer. I believe Penninkilampi provides a comprehensive and high quality review and his estimate is that women who regularly use talc powder products, defined as >3600 lifetime applications, have a 40% increased risk of ovarian cancer compared to women with no regular talc power product use. The association was significant for serous cancers. Similarly, Woolen provides a high quality review with similar results suggesting an increased risk of ovarian cancer associated with frequent perineal powder exposure of 31-65%.

__Pooled Data__

Three large studies pooled data from several studies. They are worth describing separately because of their larger sample size, and different methodology of combining studies. Each contain contributing case-control and/or cohort studies.

Terry (2013)

This report pooled data on ovarian cancer patients from a national research consortium and assessed the relationship between talc powder products exposure and ovarian cancer by histologic subtype and invasiveness. Data were from eight case-controlled studies and importantly included previously unpublished data. The authors tried to unify definitions across the studies, but the definitions nonetheless varied widely. The prevalence of genital powder use in the controls varied widely across participating study sites, ranging from 15%–45%, suggesting either large variations in the underlying populations or, probably more likely, variation in the definition of powder use that led to these differences.

The data were for a total of 8525 cases and 9859 controls in the primary analysis. The authors found that **genital talcum powder use was associated with an approximately 24% increased risk of epithelial ovarian cancer (OR 1.24, 95% CI 1.15, 1.33).** When stratified by cancer type, the risk was increased for all cancers except mucinous cancer. Risks were approximately equally elevated for invasive and borderline tumors. They used a subset of patient data to determine RR of ovarian cancer for the highest talcum powder users, measured as cumulative lifetime perineal applications (defined as applications per month and months of the year). They also considered age (inclusion in the highest user group required more use at age 70 than age 40) and assessed risk of cancer among the highest users. **The odds of cancer in the highest talc exposure category was higher than for women who ever used talc (OR 1.37, 95% CI 1.19, 1.58).** A significant dose response was seen when data on all patients were analyzed, with greater exposure leading to greater risk.

Cramer (2016)

Cramer conducted several case-control studies on the relationship between genital talc powder use and ovarian cancer. He pooled data from a large number of these studies, described as reflecting study enrollment in 1992–1997, 1998–2002, and 2003–2008. This publication reports the analysis of pooled data from these separate enrollment phases and a more detailed characterization of those data. Cases were women who resided in Eastern Massachusetts and New Hampshire diagnosed with epithelial ovarian cancer between the ages of 18 and 80. Controls were women identified through random-digit dialing, driver's license lists and town resident lists. Women were interviewed in person, and details of talc use were elicited including the number of applications per month (allowing assessment of frequency of use), timing of use, and lifetime

exposures. These descriptions gave far greater detail than most other reports and are thus an important contribution to the field. Further, more demographic, and clinical history were obtained and described in these enrollments than for other reviewed studies. This report gave associations from pooled data for 2041 cases and 2100 controls. The larger size of the population, unified variables, and greater detail about cases and controls allowed a larger number of stratifications than other studies.

Overall, genital talc use was associated with an OR of 1.33 (95% CI 1.1.6, 1.52). An important observation was that risk decreased with time since last use. Thus, how often women regularly used talcum powder (daily, or weekly or monthly) was meaningful for predicting ovarian cancer risk, but not if the women had not used talcum powder for 5 or more years. **Women who reported using talcum powder daily (>30 applications per month) had an OR of 1.46 (95% CI 1.2, 1.78)**. Of note, among women in the ovarian cancer case group who used talcum powder, daily was the most commonly reported frequency of use**. When analysis used data on women who reported their total number of talcum powder applications, those in the highest group category (>7200 lifetime applications, the equivalent of 20 years of daily application) had an OR for ovarian cancer of 1.49 (95% CI 1.06, 2.1).**

Cramer conducted detailed analysis of factors that could influence/interact with the association between talcum powder and ovarian cancer. Some of the results are quite striking. First, a very strong interaction with race was noted. **African-American women seem to be at a particularly elevated risk of ovarian cancer following talcum powder exposure (OR 5.08, 95% CI 1.32, 19.6) compared with white women (OR 1.35, 95% CI 1.17, 1.55).** This finding calls for greater research given the higher incidence, and poorer outcomes among African American women. Asian women seem to be at reduced risk (OR 0.04, 95% CI 0.01, 0.34). **Analysis showed a strong relationship with menopausal status and use of hormone replacement therapy.** ORs were significantly increased in premenopausal women (OR 1.41, 95% CI 1.13, 1.75) and **postmenopausal women who used hormone treatment (OR 2.21, 95% CI 1.63, 3.0).** Postmenopausal women who did not use hormone therapy were not at increased risk of ovarian cancer (OR 1.0, 0.68, 1.49). **Interestingly, the risk of ovarian cancer among postmenopausal hormone-treatment users was elevated only if they used hormones before hysterectomy and tubal ligation but risk was substantial (OR 3.49, 95% CI 1.39, 8.75) if talcum powder was used before these surgeries (OR 5.85, 95% CI 2.89, 11.9) compared to talcum powder use both before and after surgery.**

These findings merit further assessment in other populations but raise the possibility that estrogen is important in ovarian carcinogenesis. The authors also stratified analyses by histologic type and found that the relationship between ovarian cancer and frequency of talcum powder use was significantly elevated for invasive and borderline serous cancer and invasive endometrioid cancer, but not for mucinous, clear cell or mucinous borderline cancer. **Among the most frequent users of talc the adjusted OR for invasive serous cancer is 1.54 (95% CI 1.15, 2.07).** This relationship was even stronger among premenopausal women (OR 1.85, 95% CI 1.21, 2.8) compared to postmenopausal women (OR 1.33, 95% CI 0.96, 1.85).

O'Brien (2020)
O'Brien and colleagues performed a pooled analysis of powder use and ovarian cancer using data from the four cohort studies that assessed exposure to perineal powder. Data were included from the "Nurses' Health Study (enrollment 1976; follow-up 1982-2016; n = 81 869), Nurses' Health Study II (enrollment 1989; follow-up 2013-2017; n = 61 261), Sister Study (enrollment 2003-2009; follow-up 2003-2017; n = 40 647), and Women's Health Initiative Observational Study (enrollment 1993-1998; follow-up 1993-2017; n = 73 267)." **They report a hazard ratio of 1.08 [95%CI, 0.99 to 1.17] among women who ever versus never used powder.** In order to harmonize the measurement of the exposure across the studies, they primarily focused on quantifying the

association between ever versus never use of powder products and ovarian cancer**. They performed a number of subgroup analyses, including use among women with intact genital tracts (HR for the association between ever use of powder in the genital area and ovarian cancer risk among women with a patent reproductive tract was 1.13 (95%CI, 1.01 to 1.26), and they created a subgroup to look at frequent uses and assessed the association between powder use >= 1 x per week as HR = 1.19 (1.03 to 1.37).** There are several limitations of the pooled study, many highlighted by the letters to the editor written in response to the publication [Cramer; Harlow, Murray, and Rothman]. Rothman, a well-respected epidemiologist, and methodologist co-authored one of the letters to the editor written in response to this publication that argued the publication shows the association between perineal powder exposure and ovarian cancer. The primary limitation of O'Brien et al is the focus on *any* talcum powder use (a non-specific exposure that combines women across a very broad range of exposures). Although the authors looked at frequent use greater or equal to 1 x per week, only two studies contributed meaningfully to this estimate (NHS I and Sisters Study.) The Women's Health Initiative did not ask about frequency of use so the data from that study could not be included in the assessment of powder use >=1 x per week. Further the NHS II study had a very short period of follow up after adding the question of talcum powder use to their survey - fewer than 10% the person-time at risk and < 6% the number of ovarian cancer cases compared with the NHS I. This means the NHSII contributed few meaningful data. Further, although the Sister Study is included, this study asked about exposure in two discreet periods of time that may not reflect overall use and included in their assessment of exposure, sanitary pad application of powder. This is not generally included with perineal exposures. Thus O'Brien used few data from the cohort studies to answer this question about the use of powder and ovarian cancer. Other limitations of their pooled study included inconsistency in the exposure (lack of specificity of the type of powder used - none of the cohorts asked whether talcum powder or cornstarch was used), and the extended time period between when talc use was assessed and assessment of cancer outcomes (leading to a selection bias known as depletion of susceptibles). This pooled data has limited usefulness in assessing the relationship between talcum powder use and ovarian cancer, in large part because it ignored most of the published literature.

Davis (2021)

Davis and colleagues completed a pooled data study to specifically address risk among African American women. Genital powder use is higher among African American compared with women (36% vs 30%,) and therefore it is particularly important to assess the risk of ovarian cancer in African American women exposed at higher rates. Recent research suggests the elevation in ovarian cancer risks associated with talcum powder exposure is similar in African American and white women. The Ovarian Cancer in Women of African Ancestry (OCWAA) consortium was established with the objective to understand racial differences in risk and outcomes associated with epithelial ovarian cancer. Using five of the eight OCWAA studies that collected data on body powder use, Davis et al. evaluated the association between exposure of talcum powder products and ovarian cancer. The study included four population-based case-control studies (the North Carolina Ovarian Cancer Study, Los Angeles County Ovarian Cancer Study, Cook County Study and African American Cancer Epidemiology Study) and a nested case-control study within the WHI Observational Study. Genital powder use was assessed prior to 2014 and ovarian cancer risks by race were assessed using logistic regression. Ever use of genital powder was associated with an elevated odds of ovarian cancer among African American women [OR = 1.22; 95% confidence interval (CI) = 0.97-1.53] and White women (OR = 1.36; 95% CI = 1.19-1.57). In African American women, the positive association with risk was greater among high-grade serous tumors (OR = 1.31; 95% CI = 1.01-1.71) whereas among White women the risks did not vary by histology.

Pooled Data Studies: Summary

The increased risk of ovarian cancer associated with talc use was estimated at around 20%-40% across studies. The increased risk for serous cancer was even higher. The increased risk of ovarian cancer associated with

powder use was around 13% in the pooling of data from the cohort study among women with intact fallopian tubes, however this reflects ever talc use, and the details of this study reveal many biases that would be expected to underestimate risk (e.g., biases toward the null). African American and white women have similar elevated risks associated with talcum powder exposures although the association with serous tumors in particular was higher in African American women.

<u>Case-Control Trials</u>
A large number of case-control studies are published—too many to dedicate a paragraph to summarizing the methods of each. The studies are listed in Tables 3 and 4. I carefully read and reviewed each study. All but two demonstrated a positive association (OR > 1) between any talc powder products use and ovarian cancer, with ORs ranging from 0.73–3.9 across studies. The measure of the association across these studies is best summarized using quantitative meta-analytic techniques, as done in the systematic reviews described above.

V. Health Canada Screening Assessment (2021)

The Canadian Minister of the Environment and the Minister of Health conducted a detailed and comprehensive assessment of whether the genital use of talcum powder caused ovarian cancer, including a Bradford Hill analysis. The assessment focused on the health effects of cosmetic-grade talc and did not consider potential impurities such as asbestos (thus they didn't consider the even greater risks associated with talc as it is now known to contain asbestos and/or asbestiform talc as described above). The ecological portion of the assessment was subject to an external peer review and a 60-day public comment period. The human health portion of this assessment underwent external peer review and/or consultation. Health Canada reached similar conclusions as described in this report. The authors concluded that the available data are indicative of a causal effect. They describe factors that strongly supported their conclusion including 1) the strength of the epidemiological data demonstrating consistency in the epidemiological studies across several decades and conducted in different parts of the world with statistically significant pooled ORs from available meta-analyses with narrow confidence intervals. 2) strong evidence of a viable mechanism that talc particles migrate from the vagina to the fallopian tubes and ovaries following perineal application. 3) that there is evidence that inflammation can be triggered by talc and that there is an association between inflammation and ovarian cancer supporting the biological plausibility.

VI. Summary of the Epidemiology Data, Association Between Talcum Powder Products and Ovarian Cancer

I conclude, based on the review of the available primary studies, systematic reviews, and the Health Canada Report that regular exposure to talcum powder products increases ovarian cancer risk by around 40-50%. The strongest and largest systematic reviews (Penninkilampi and Berge) and the Woolen review that specifically focuses on regular users, also conclude a significant increase in ovarian cancer risks occur following talcum powder exposure. And the Health Canada Report similarly concluded that the available data are indicative of a causal effect between perineal exposure to talc and ovarian cancer.

VII. Other Relevant Factors

<u>Research Supporting Talcum Powder Association with Ovarian Cancer: Transit to Ovary and Risk Reduction on Interruption</u>
Evidence from relevant studies is clear that talcum powder particles applied to the genital region will ascend through the vagina and fallopian tubes and enter the pelvic cavity, reaching fallopian tubes and ovaries. In humans, this route has been established experimentally by labelling inert particles, depositing them in the

vagina just prior to planned hysterectomy, and then recovering them from the fallopian tubes following surgery.(Egli and Newton 1961) Other substances that have been shown to migrate through the open female genital tract include nonmotile sperm (Jones and Lopez 2006), retrograde menstruation (Blumenkrantz 1981), particulate radioactive material (Venter and Iturralde 1979), and glove powder (Sjosten 2004). This transport is facilitated by a uterine “peristaltic pump”. (Kunz 1997)

Further, talc particles have been found in normal and malignant ovarian tissue. Henderson found that in 10 of 13 tested epithelial ovarian cancer tumors, 75% had talc embedded in the tissue. This result confirms that talc reached to the areas with cancerous tissue, but not that it caused the cancer. Histological evaluation of ovaries removed because of ovarian cancer or benign conditions have identified both talc particles and asbestos fibers in the ovarian tissue, further supporting that particles applied to the perineum reach the ovaries. (Heller 1996) Heller found that in all women in a study who were having ovaries removed for benign ovarian growth had talc in their ovaries. These results confirm that talcum powder applied to the perineum may be absorbed into the vagina and migrate or be transported to the tubes and ovaries. In 1967, Graham and Graham demonstrated that intraperitoneal application of asbestos in guinea pigs and rats results in overgrowth of ovarian epithelial cells comparable to the histologic changes in epithelial ovarian tumors in women. (Graham 1967) The greater frequency at which talc particles are discovered in ovarian cancerous tissue than in normal ovarian tissue further supports that these particles may be causing cancer. More recently, talc particles have been described in lymph nodes and other pelvic organs. (Cramer 2007, McDonald 2019)

Several epidemiological studies evaluated the risk of ovarian cancer associated with talcum powder products before and after women had tubal ligation or hysterectomy, which surgically removes the route by which talc reaches the ovaries. The studies strongly suggest that the increased risk of ovarian cancer associated with talcum powder products use is reduced or eliminated after tubal ligation or hysterectomy. The results support that the risk from talcum powder products is elevated when women have an open pathway from the perineum to the ovary that enables powder components to reach the ovaries via unobstructed fallopian tubes. The collective results demonstrate that talcum powder products are carcinogenic through direct transport/migration to the fallopian tubes and ovaries.

<u>Variation in Risk when Talc Use is Discontinued</u>
Several studies showed that the risk of ovarian cancer associated with talc powder products decreases as the time from discontinuation of powder use increases. For example, Cramer found an elevated risk of ovarian cancer with talc powder products use and the risk decreased as time since last use increased. (Cramer 2016)

VIII Consideration of Causality of Talc Powder Products and Ovarian Cancer: Bradford Hill Analysis

There is no simple approach for determining if a particular exposure (like exposure to talc powder products) *causes* a disease (like ovarian cancer). (Rothman 2008) In biomedical research, causality is easiest to determine in studies that employ a randomized controlled trial design, in which participants are randomized to receive or not receive a treatment or exposure, then their health is followed to see their response. However, people cannot ethically be randomized to be exposed to a potentially cancer-causing agent and further, sometimes even randomized trials give results that are inconclusive. When assessing risk factors for cancer, it is important to look at the totality of evidence. An approach put forth in 1965 by Sir Austin Bradford Hill (frequently called the Bradford Hill Factors), and that was an expansion of a long list of criteria put forth by others in the decades and centuries preceding him (Rothman 2008), are often used to assess the totality of the evidence. They provide a framework for assessing the weight of evidence to help decide if causality is likely,

given a particular association, such as between talcum powder and ovarian cancer. The guidelines are imperfect and while they provide a framework, they are not an absolute set of criteria.

I address each of the Bradford Hill factors below, with my understanding of how the evidence of talcum powder products exposure supports or refutes causality. While the Bradford Hill Factors include nine aspects of association, it is important to emphasize that they should not be used as a checklist for causation. Instead, they can help interpret associations and aid in inferring causality. For each factor, I have highlighted why I believe this factor is more or less important.

A) Strength of Association

It is frequently argued that the larger an apparent association, the more likely the association is to be real (causal) and important for epidemiological assessment. This would suggest that an OR of 2.0 is more likely to indicate causality and importance than an OR of 1.5. While this is often argued, this is untrue. (Rothman 2016; Rothman and Poole 1988) If there is a true association that increases the risk of disease (effect size) by 20%, good scientific studies will estimate the effect size at 20%. Further with respect to the impact of that risk on the population, if a risk factor increases the risk of disease by 50%, and the exposure is common, it will have a far greater impact on a number of people impacted, in comparison to a rare exposure that has a higher associated relative risk. And if the association is truly one that increases risk by 50%, that this association can be discoverable. Perhaps a larger association between exposure and disease may be easier to identify, but it is no more likely to indicate causality or importance. (Rothman 2008) Further, the impact of a risk factor may be understood both as a relative increase in disease (reflected by a risk ratio, odds ratio, etc.), and it can also be understood as a difference in risk which more fully will reflect the number of individuals impacted.

An Example to Help Frame Consideration of the Relative Strength of Association, and Number Impacted.

As an example, Table 5 shows an overview of the relationship between bladder cancer and two of its well known risk factors; occupational industrial chemicals and smoking. Several industrial chemicals such as 2-naphthylamine are strongly associated with bladder cancer risk. In 1954, Case et al. reported a 200-fold increased bladder cancer risk for workers exposed to 2-naphthylamine. In cohort studies of rubber industry workers, elevated standardized mortality ratios (SMRs) as high as 253 (95% CI 93, 551) were reported. Use of some of these chemicals are now prohibited in Europe and their use is regulated in the United States because they cause cancer. (OSHA, 2011). Cigarette smoking is also a known bladder cancer risk factor. However, the RR for smoking and bladder cancer is around 3, and therefore about 100 times lower than the RR for exposure to industrial chemicals. An exposure to industrial chemicals is far worse, and more likely to result in bladder cancer in comparison to cigarette smoking. Yet bladder cancer is the second most common cancer attributed to smoking in the United States. It impacts a very large number of individuals. Of the 70,000 cases of bladder cancer diagnosed each year, as many as 60% are estimated as attributable to smoking, whereas a tiny fraction is attributable to industrial chemicals.

Using the relative risk (effect size) to understand the “importance” of these two risk factors (industrial chemicals and smoking) with respect to causing cancer in the U.S., would be misleading. Smoking will result in far more cancers than industrial chemicals, even though the relative risk is much lower. In the crude sample data included in Table 5 to highlight this comparison, of the approximately 70,000 bladder cancers diagnosed annually in the United States, 50,000 are thought to result from cigarettes while fewer than 1000 result from occupational exposures. A 50% reduction in exposure to smoking will save approximately 25,000 men from getting bladder cancer. Reducing industrial chemical exposures by 50% will save approximately 500 men from getting bladder cancer. Thus, any impact on reducing known exposures for bladder cancer has the potential to be around 50 times more impactful if directed at smoking.

Table 5. An example showing the number of individuals who might be impacted through exposure to an occupational chemical that leads to bladder cancer as opposed to smoking which also leads to bladder cancer. The Table highlights that the relative effect size from a given exposure does not predict the number of patients impacted; rather it's important to take into consideration both the effect size and the number of individuals exposed.

	Occupational Exposure 2-naphthylamine	**Smoking**
Estimated odds ratio associated with exposure	200	3
Number of individuals exposed annually	10,000	50,000,000
Annual bladder cancers diagnosed annually from exposure	1000	50,000
Impact on number of cancers diagnosed annual if exposure reduced by 50%	500	25,000

Strength of Association, Talc Powder Products and Ovarian Cancer

The bladder cancer example highlights that when comparing two risk factors, it is not necessarily the relative risk factor with the greatest relative risk that is most important. A risk factor that increases risks by 50% will have an enormous impact on population mortality if the exposure is common or if the cancer is particularly lethal. This is certainly the case for talcum powder products, which are used by as many as half of all women in the United States. Women's use of talcum powder products is so widespread that even a relatively modest increase in risk would pose a sizeable health risk to the population. Further, a 50% risk increase is substantial and particularly important for ovarian cancer, which has a high mortality rate, with rare early detection.

Defining the association is critical for assessing potentially causal relationships, but that is not defined by a set cutoff or threshold to define a strong association. A current concept in epidemiology is that considerations about whether a factor causes a disease should weigh statistical validity along with the multiple factors that influence the disease. Thus, assessing *strength of association* when inferring causality requires examining underlying research and analytic methods, comparing the weight of evidence in the literature, and considering other contextual factors. The data supporting the causality of talcum powder products exposure for ovarian cancer is extremely strong.

Estimating the Impact of Talc Powder Product Use and Ovarian Cancer Cases in the U.S.

Relying on the evidence that I assembled and reviewed for this report, I estimated how many and what percent of ovarian cancers that occur each year in the United States are likely to be caused by exposure to talcum powder products, Table 6. This is a relatively simple analysis, but nonetheless is informative. The purpose of this analysis is to help elucidate the relationship between the strength of the association and the number of people impacted.

The total number of ovarian cancers that are estimated to occur in the US annually in 2018 was 22,240, and these will occur among the 50.8 percent of the U.S. population of 311 million who are women (158 million). A proportion of ovarian cancers will occur among women who regularly use talcum powder products, and the remainder will occur in women who do not regularly use talcum powder products. For this calculation I have estimated that women exposed to talcum powder products less than regularly do not have an increase in their underlying ovarian cancer risk. I estimate that women who use talcum powder products regularly have approximately a 50% elevated risk of ovarian cancer and make projections estimating number of women who are exposed regularly to talcum powder products ranges from 10% and 60%. Using these model inputs,

between 3,177 and 15,397 women who regularly use talcum powder products will be diagnosed each year with ovarian cancer, reflecting 14% and 69% of all ovarian cancer cases. Attributable risk is the portion of disease attributable to the exposure. Approximately 1/3 of these cancers are attributable to the use of talcum powder use (ranging from 1059 to 5,132 depending on how many women are regular users of talcum powder products). This reflects that between 5% - 23% of all ovarian cancer diagnosed each year in the U.S. are attributable to exposure to talcum powder products, varying by the underlying proportion of women who regularly use talcum powder products. <u>This is a tremendous number of cases caused by a cosmetic product that provides no medical benefit. The Bradford Hill Factor of the strength of association is met.</u>

Table 6. An estimate and projection of the number and percent of ovarian cancers caused by regular use of perineal talc powder products in the U.S. varying the underlying proportion of women who regularly use talcum powder products.

Ovarian Cancers Diagnosed annually	**22,250**
US population of women	**158,000,000**

	Women		Cancer	Cancers Diagnosed Annually		Proportion of Cancers Diagnosed Annually		Cancer Incidence per 10,000		Attributable Rsk			
Percent of women who use talcum powder products	Do not regularly use talcum powder products	Regularly use talcum powder products	Cancers diagnosed annually, all women	In women who do not regularly use talcum powder products	In women who regularly use talcum powder products	In women who do not regularly use talcum powder products	In women who regularly use talcum powder products	In women who not regularly use talcum powder products	In women who regularly use talcum powder products		Cases in women who use talcum powder products diagnosed annually attributable to the use of talcum powder products	Proportion attributable risk, proportion of cases in women who use talcum powder products attributable to their use of talc	Proportion of All Ovarian Cancer In All Women Attributable to Talc
10%	142,200,000	15,800,000	22240	19,063	3,177	0.86	0.14	0.000134	0.000201	0.000067	1,059	0.33	0.05
20%	126,400,000	31,600,000	22240	16,175	6,065	0.73	0.27	0.000128	0.000192	0.000064	2,022	0.33	0.09
30%	110,600,000	47,400,000	22240	13,537	8,703	0.61	0.39	0.000122	0.000184	0.000061	2,901	0.33	0.13
50%	79,000,000	79,000,000	22240	8,896	13,344	0.40	0.60	0.000113	0.000169	0.000056	4,448	0.33	0.20
60%	63,200,000	94,800,000	22240	6,843	15,397	0.31	0.69	0.000108	0.000162	0.000054	5,132	0.33	0.23

<u>B) Consistency of Associations in Different Populations and Studies</u>

Another consideration for association and causality is consistency of the data. The data on the association between genital talc and ovarian cancer are highly consistent. The relative stability in the estimated increase in the risk of ovarian cancer associated with talc powder products use (50% increase for regular users of talcum powder and serous cancers; around 40% increase for all epithelial ovarian cancer and regular users of talcum powder products), as assessed across time and in diverse populations with diverse study designs, <u>strongly argues that the causal association is real and satisfies the Bradford Hill guideline for consistency of associations across populations and studies.</u>

<u>C) Specificity Between Cause and Effect</u>

The Bradford Hill factors suggest that associations are more likely to be causal when an exposure causes only one disease. While some examples of highly specific exposures and outcomes exist, many exposures and health concerns involve complex chemical mixtures and low-dose environmental and occupational exposures complicated by a variety of personal risk factors. A recent review stated, <u>"The original criterion of *specificity* is widely considered weak or irrelevant from an epidemiologic standpoint</u>." (Fedak 2015) Asbestos, for example, is associated with a range of cancers and various exposures. Regardless of doubts about the meaningfulness of this factor, talcum powder products are associated with ovarian cancer (e.g., not uterine or breast cancer as seen in O'Brien 2024) and thus fulfills the specificity consideration, although this consideration is not an important consideration for causality in my expert opinion.

D) Temporality

An exposure must come before an outcome for the exposure to be causal. Bradford Hill explained that for an exposure-disease relationship to be causal, exposure must precede the onset of disease. While this is self-evident, in epidemiological studies, reverse causality, in which behavior related to a health issue is influenced by knowledge or events about the issue, is always a concern. For example, women who undergo ovarian cancer treatment may begin using talcum powder products during their pre- and post-operative period because of symptoms or side effects perceived to be alleviated by talcum powder products use. Assessing talcum powder use without specifying the time of use might lead to women with ovarian cancer being more likely to report talcum powder products use. In this example, talcum powder may not have caused the cancer; rather, use of talcum powder products was caused by the cancer (and treatments). The importance of this issue led to Bradford Hill's consideration of temporality when assessing causality.

In essentially all of the case-control studies that assessed use of talcum powder products, women were specifically asked to report talc powder products only during past, not current periods; thus, the studies explicitly assessed exposure to talcum before cancer. Typically, questions were phrased "Did you ever use talc, but not in the last year before cancer diagnosis?" to exclude the year prior to diagnosis. This issue is not relevant for the included cohort studies, as women were surveyed about their exposures prior to cancer ascertainment. Thus, the temporality consideration is important for my consideration and is satisfied.

E) Dose Response

In general, when risks are proportional to exposure (e.g., doubling exposure doubles risk) this dose-response evidence is considered to support causality. While some of the published studies did not collect sufficient data to carefully quantify the dose response, most did, including the results of the NHS 1 cohort (O'Brien 2020) and the Sisters cohort (O'Brien 2024) that found a dose response relationship. The systematic reviews summarizing these individual studies including Taher (2019), Penninkilampi (2018), and Berge (2018) all confirm a dose response relationship where women with more lifetime applications had higher risks as did women who reported long-term talc use or the most applications. Additionally, the Woolen systematic review (2022) included new and updated data from the Nurse's Health Study cohort, shows greater risks among frequent daily talc users compared with less frequent users. Thus most studies of talcum powder products and ovarian cancer show a dose response, with the caveat that some studies do not, and several studies did not assess. However, this factor does not weight heavily in my consideration in that not all exposures known to be carcinogenic will have a dose response, as some will have a threshold effect. This is important here because asbestos is believed to exhibit a threshold, rather than a linear, dose-response. Thus the observed dose response relationship supports the causality of talcum powder products and ovarian cancer, its absence in any given study would not dissuade me from my belief that talcum powder products causes ovarian cancer in some women.

F) Biologic Plausibility: Factors Linking Talc and Ovarian Cancer

The epidemiological evidence suggests a strong and positive association between exposure to talcum powder products and invasive ovarian cancer. However, epidemiological evidence alone does not provide a mechanism or pathophysiological process that accounts for the increased risk. Nor does the epidemiological evidence confirm the specific component or ingredient in talc powder products that is responsible for carcinogenesis. Nonetheless, the data are persuasive that particles contained in talcum powder reach the tubes and ovaries, inflammation as well as other biological process, initiate a causal pathway, and that several components of talc powder products including asbestos, asbestiform talc fibers, and heavy metals (Group 1 carcinogens by the evaluation of IARC) can all contribute to the carcinogenicity of the products. This was a

strong factor in my consideration of the evidence because there is extremely strong evidence that the components of talc powder products are known to be highly carcinogenic in other settings.

G) Coherence and Consistency with Understood Biology
The guideline of coherence is considered similar to biological plausibility. For both, the cause-and-effect explanation should be consistent with all knowledge available. For talcum powder and ovarian cancer, this consideration is easily satisfied.

H) Experimental Evidence
The evidence in humans of the impact of talcum powder products exposure and ovarian cancer development is based on a large number of observational studies. Direct experimental evidence in the form of randomized controlled trials in humans is simply not possible to generate, for ethical reasons. The experimental evidence in humans that talc particles can migrate to the ovary and be incorporated into ovarian tissue is relevant to developing a causal model but does not directly prove that that exposure causes cancer. There is also human data relating to the inflammatory nature of ovarian cancer. There is compelling in vitro research delineating the inflammatory mechanism by which talcum powder causes cancer. Animal studies showing inflammatory tissue effects and tumor formation with talcum powder exposure are also supportive.

I) Analogy
Bradford Hill implied that when evidence is strong of a causal relationship between a risk factor and disease, researchers should be more accepting of weaker evidence that a similar risk factor may cause a similar disease. Thus, analogy has been interpreted to mean that when one causal agent is known, the standards of evidence are lowered for a second causal agent that is similar. The strong evidence for the association between asbestos and lung cancer, and the chemical similarity between these minerals, as well as their fibrous nature, supports the analogy consideration and causal inference.

IX Bradford Hill - Summary: Consideration of Causality of Talc Powder Products and Ovarian Cancer

In consideration of the Bradford Hill factors, the clear strength of the association (A), remarkable consistency in the published literature across a large number of populations and research studies (B), temporality (D) considered in all of the published studies, and Dose Response (E)and perhaps most importantly, biological plausibility (F) were the criteria that I considered of paramount importance when assessing the causality of exposures of talc powder products and epithelial ovarian cancer.

X Conclusion

In conclusion, substantial evidence supports a strong, positive, and causal association between ovarian cancer and genital exposure to Johnson's Baby Powder and Shower to Shower products. Regular exposure to these talcum powder products causes ovarian cancer in some women. This opinion is based on my extensive review of the medical and scientific literature, my own independent systematic meta-analysis of the data, and my experience and expertise in the areas of epidemiology and women's health, including ovarian cancer.

All opinions are made to a reasonable degree of medical and scientific certainty. I reserve the right to amend or supplement this report as new information becomes available. I also reserve the right to review and comment on the expert reports and testimony of Defendants' experts.

Sample of References Cited.

Please see full list of references reviewed for this report.

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Exhibit A

Prepared: March 9, 2024

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EDUCATION

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1985 - 1986	Columbia University	Postbaccalaureate	Pre-Medical Program
1987 - 1991	University of California, San Francisco	MD	Medicine
1991 - 1992	University of California, San Francisco	Intern	Pathology
1992 - 1996	University of California, San Francisco	Resident	Radiology
1996 - 1997	University of California, San Francisco	Clinical Instructor	Radiology, Ultrasound
1996 - 1998	University of California, San Francisco	Fellow	Epidemiology & Biostatistics

LICENSES, CERTIFICATION

1992	California Medical License # G76462
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PRINCIPAL POSITIONS HELD

1998 - 2003	University of California, San Francisco	Assistant Professor	Radiology, Epidemiology and Biostatistics, Obstetrics , Gynecology and Reproductive Science
2003 - 2009	University of California, San Francisco	Associate Professor	Radiology, Epidemiology and Biostatistics, Obstetrics , Gynecology and Reproductive Science
2009 - 2021	University of California, San Francisco	Professor	Radiology, Epidemiology and Biostatistics, Obstetrics, Gynecology and Reproductive Science
2009 - present	University of California, San Francisco	Professor	Epidemiology and Biostatistics, Obstetrics , Gynecology and Reproductive Science
2014 - present	University of California, San Francisco	Affiliate member	Phillip Lee Institute for Health Policy Studies
2000 - present	University of California, San Franciso	Director	Radiology Outcomes Research Laboratory

OTHER POSITIONS HELD CONCURRENTLY

1999 - 2000	The Royal London School of Medicine	Visiting Research Fellow

2000 - present	University of California, San Francisco	Director, Radiology Outcomes Research Lab (RORL)
2009 - 2010	National Institutes of Health	Visiting Research Scientist

HONORS AND AWARDS

1985	Cum laude, Princeton University
1985	Senior Thesis Prize, Princeton University
1991	Student Summer Research Fellowship, Institute for Health Policy, UCSF
1999	Nycomed Amersham Fellow, Radiologic Society of North America
2000	Nycomed Amersham Fellow, Radiologic Society of North America
2007	Nomination, Clinical Research Mentor of the Year, Bay Area Symposium on Clinical Research
2007	Nomination CTSI Mentoring Consultant of the Year
2010	Nomination, CTSI Consultant of the Year, Impact Award
2010	Scientific Paper of the Year, Minnies, Auntminnie.com
2010	Finalist, Most Influential Radiology Researcher, Minnies, Auntminnie.com
2011	Leader in Imaging, Auntminnie.com
2012	Finalist, Scientific Paper of the Year, Auntminnie.com, Minnies
2012	Semifinalist, Scientific Paper of the Year, Auntminnie.com, Minnies
2012	Winner, UCSF Center for Health Care Value, Medical Center Initiative, Call for Innovation Proposals
2013	Finalist, Scientific Paper of the Year, Auntminnie.com, Minnies

2013	Runner-up, Scientific Paper of the Year, Auntminnie.com, Minnies
2013	Paper Honored as One of the Top 10 Publications in 2013 Funded by NCI's Epidemiology and Genomics Research Program
2014	Invited Editor, Journal of the American College of Radiology March 2014 Issue, Radiation Dose Optimization
2014	Among 26 Philip R. Lee Institute for Health Policy Studies faculty videos posted on UCTV between 2009 and 2014, the video recorded of talk given by Dr. Smith-Bindman, "Is Medical Imaging Harmful to Health: Opportunities to Influence Health Policy", was the most frequently downloaded and watched (N = 409,937)
2015	Distinguished Investigator Award, Academy of Radiology Research
2015	Election to Fellowship, Society of Radiologists in Ultrasound
2019	UCSF Academic Senate 19th Annual Faculty Research Lectureship □ Clinical Science; □Computed Tomography: A Medical Triumph Fostering a Silent Epidemic□

KEYWORDS/AREAS OF INTEREST

Health Services Research, Outcomes Research, Disparities Research, Women's Imaging, Comparative Effectiveness Research, Quality Improvement, Dissemination and Implementation Sciences, Evidence Based Radiology, Assessment of Population Impact of Screening Tests, Radiation Associated with Medical Imaging, Radiation as an Environmental Cause of Cancer, Management of Incidental Findings on Diagnostic Testing

CLINICAL ACTIVITIES

CLINICAL ACTIVITIES SUMMARY

Attending physician, Ultrasound Section, Department of Radiology and Biomedical Imaging, UCSF. The work Includes supervised instruction of residents and fellows. My teaching on the service focuses on how to use evidence to help inform interpretation of clinical examinations and the mentoring of the trainees on research projects.

PROFESSIONAL ACTIVITIES

MEMBERSHIPS

1997 - 2021	Society of Radiologists in Ultrasound (SRU)
1997 - 2016	Radiology Alliance for Health Services Research in Radiology (RAHSR)
2013 - 2016	American College of Radiology (ACR)
2014 - 2016	American Roentgen Ray Society (ARRS)
2014 - 2016	Association of University Radiologists (AUR)
2018 - 2021	Radiological Society of North America (RSNA)

SERVICE TO PROFESSIONAL ORGANIZATIONS

2001 - 2002	Society of Health Services Research in Radiology, Program and Rules Committee	Committee Member
2002 - 2005	Cochrane Collaboration Screening and Diagnostic Tests, Methods Working Group	Contributor
2003 - 2003	Radiology National Boards, Examination Question Writer	Contributor
2005 - 2005	Institute of Medicine Report, Improving Mammography Quality Standards	External Reviewer
2010 - 2011	American Board of Medical Specialties, American Board of Radiology, American College of Radiology and Physician Consortium for Performance Improvements. Patient Radiation Dose Work Group	Committee Member
2010 - 2011	National Quality Forum, Imaging Efficiently Steering Committee	Steering Committee Member
2010 - 2011	American Board of Medical Specialties, American Board of Radiology, American College of Radiology and Physician Consortium for Performance Improvements. Patient Radiation Dose Work Group	Committee Member
2010 - 2011	Lung Cancer Screen with CT, Evidence Review Committee, Multidisciplinary & Society Collaboration, Including American Cancer Society; American College of Chest Physicians; American Society of Clinical Oncology & National Comprehensive Cancer Network	Review Committee
2011 - 2012	Institute of Medicine (IOM), Commissioned Report for the IOM Committee on Breast Cancer and the Environment. Paper entitled Temporal Changes in Ionizing Radiation and Estimate of Contributions to Breast Cancer	Author of Commissioned Report

2011 - 2014	Auntminnie, Minnie Selected Committee	Expert Panelist/Committee Member
2012 - 2014	The Joint Commission, Diagnostic Ionizing Radiation and Magnetic Resonance work group. Group focused on Safety and Guideline Development	Expert Panel Committee Member
2012 - 2014	CDC Cancer Prevention Work Group	Committee Member
2013 - 2015	Auntminnie, Selection of Minnie Winners	Expert Panelist, Committee Member
2014 - 2014	International Atomic Energy Agency, United Nations General Assembly and Security Council, Special Committee Considering Population Impact of Low Dose Radiation	Committee Member Considering Population Impact of Low Dose Radiation
2011 - 2021	International Council on Radiation Protection, Task Group 79 on Effective Dose	Committee Member
2012 - 2021	International Council on Radiation Protection, Task Group 79 on Defining the Effective Dose in Medicine	Task Group Member
2015 - present	Council of Distinguished Investigators of the Academy of Radiology Research	Member
2019 - 2021	American Urological Association (AUA) Committee to Draft Guidelines on Microscopic Hematuria Evaluation	Committee Member

SERVICE TO PROFESSIONAL PUBLICATIONS

2000 - present	Journal of the American Medical Association (JAMA)
2000 - present	JAMA Internal Medicine
2000 - present	New England Journal of Medicine
2000 - 2020	Radiology
2000 - 2016	American Journal of Radiology
2000 - 2011	Journal of the National Cancer Institute
2000 - 2011	Health Affairs
2000 - 2010	American Journal of Medicine
2000 - 2010	American Journal of Obstetrics & Gynecology
2000 - 2010	American Journal of Public Health
2000 - 2010	Annals of Internal Medicine
2000 - 2010	Journal of Medical Screening
2000 - 2010	Journal of Women's Health

2000 - 2010	Medical Care	
2000 - 2010	Medical Decision Making	
2000 - 2010	Obstetrics and Gynecology	
2000 - 2010	Ultrasound in Obstetrics & Gynecology	

INVITED PRESENTATIONS - INTERNATIONAL

2001	US - UK Cancer Learning Network, Deprivation and Cancer; London, United Kingdom	
2001	British Society of Human Genetics, Prenatal Screening for Down syndrome in England and Wales and Birth Outcomes; London, United Kingdom	
2002	Global Summit on Mammographic Screening, Europe Institute of Oncology; Milan, Italy	
2005	U.S.-U.K. Comparison of Screening Mammography, Does Practice Make Perfect; Association Between Volume and Accuracy of Mammography; University of Copenhagen, Denmark	
2005	Continuing Education: Cancer Screening For Radiologists, Montreal and Quebec, Canada	Speaker
2006	International Society for Prenatal Diagnosis, Prenatal Screening For Down Syndrome in The Second Trimester of Pregnancy Kyoto; Japan, 2006	
2009	Canadian Breast Cancer Foundation, Forum on the Earlier Detection and Diagnosis of Breast Cancer; Toronto, Canada, 2009 Mammography Quality	
2010	Nation Cancer Research Institute (NCRI), Liverpool, United Kingdom: "Risk of Cancer from Computed Tomography (CT) Examinations"	
2013	Bach Mai University Hospital, Hanoi, Vietnam: "Radiation for Medical Imaging: A Hidden Epidemic"	
2013	UCSF Radiation Safety and CT: A Virtual Symposium, □Radiation from Medical Imaging: A Hidden Epidemic□, □UCDOSE Collaborative Project Across the UC Medical Centers□, □The National Quality Forum UCSF CT Radiation Dose Measure□, □Radiation Dose Across Large Integrated Health Care Systems" (Online)	
2014	International Atomic Energy Agency (IAEA), Health Effects of Exposure to Low Dose Ionizing Radiation Associated with Medical Imaging, Vienna, Austria	

2014	Korea College of Radiology, Tracking and Monitoring Radiation Dose and Its Impact Across the University of California Medical Centers and CT Radiation Doses Are Not What You Think: Why It's Important to Monitor and Track Dose Seoul, Republic of Korea
2016	International Atomic Energy Agency (IAEA), Exposure to low dose ionizing radiation from medical imaging and the health effects from these exposures. International Atomic Energy Agency. Technical Meeting on Science, Technology and Society Perspectives on Nuclear Science, Radiation and Human Health: The View from Asia, Singapore University
2016	University of North Carolina School of Medicine, Chapill Hill, NC, Radiology Department Grand Rounds , Diagnostic Imaging: Increasing Effectiveness and Safety Radiation From Medical Imaging,
2016	Singapore General Hospital, Singapore. Radiology Grand Rounds. Visualizing Patients and Their Dose to Improve Health Care Quality,
2016	St Luke's International Hospital, Tokyo, Japan. Hospital-wide grand rounds, Radiation from Medical imaging: A Hidden Epidemic.
2017	Childhood Leukemia International Consortium, Annual Meeting, Minneapolis, Minnesota, Estimating Radiation Exposure from Imaging Procedures
2017	Charity Hospital, Berlin, Germany. Radiology Grand Rounds, Radiation from Medical Imaging: A Hidden Epidemic
2017	Charity Hospital, Berlin, Germany, Imaging for Suspected Nephrolithiasis: Results from the Randomized Controlled Trial
2017	University Hospital, Basel, Switzerland, Radiology Grand Rounds. A Dose of Reality: The Need for Active CT Dose Management
2018	Jakarta Radiology Society, Jakarta Indonesia. Dose Optimization Implementation to achieve better radiology service in HospitalKeynote Addresses: Radiation from Medical Imaging: A Hidden Epidemic and Optimizing Radiation Doses for CT
2018	Westmead Hospital Sydney Australia. Radiology Grand Rounds. Radiation from Medical Imaging: A Hidden Epidemic

2018	Westmead Children's Hospital, Sydney Australia. Grand Rounds. Optimizing Radiation Doses For Pediatric CT
2021	Primer Congreso Internacional De Oncología Pediatric, "Utilization of Computed Tomography, Exposures to Ionizing Radiation, and Associated Cancer Risks." Hospital Infantil Hospital Infantil Teletón de Oncología, México
2021	RSNA (Radiological Society of North America), Chasing the Holy Grail: Reducing Radiation Dose and Improving Image Quality
2021	RSNA , Radiological Society of North America), An Introduction to The Learning Health Care System Pragmatic Trials - Yes We Can Randomize!
2021	RSNA (Radiological Society of North America) Radiation from CT: a Hidden Epidemic
2021	RSNA (Radiological Society of North America), Protocol Optimization for Low Dose CT
2021	RSNA (Radiological Society of North America), Controversies in Imaging Utilization
2023	RSNA (Radiological Society of North America) Radiation from CT: a Hidden Epidemic
2023	ISORED - International Society for Radiation Epidemiology and Dosimetry, 1st Scientific Meeting, Sitges Spain. Radiation Dose Associated with Common CT Examinations Over Time in the US and Ontario Canada

INVITED PRESENTATIONS - NATIONAL

2000	American College of Medical Genetics
2000	Society of Radiologists in Ultrasound
2000	Society for Health Services Research in Radiology
2001	Society of Radiologists in Ultrasound Annual Meeting
2001	Society for Health Services Research in Radiology
2002	Society of Radiologists in Ultrasound
2003	Breast Cancer Surveillance Consortium
2003	Society of Radiologists in Ultrasound
2003	Centers for Disease Control and Prevention
2003	RSNA 88th Scientific Assembly and Annual Meeting
2004	Saving Women's Lives: Institute of Medicine (IOM)

2004	Breast Cancer Surveillance Consortium
2005	Improving Mammographic Quality Standards Institute of Medicine (IOM)
2006	Beth Israel Deaconess Medical Center
2006	National Institute Child Health and Human Development
2007	National Cancer Institute, National Institute of Health
2007	National Cancer Institute, National Institute of Health
2008	Mount Sinai Urban Health Institute; Metro Chicago Breast Cancer Taskforce: "Partnerships in Translation: Advancing Research and Clinical Care"
2008	Grand Rounds, and Visiting Professor, University of Washington, Seattle, Washington
2008	4th Annual HMO Research Network Conference, Danville, Pennsylvania
2009	Society of Radiologists in Ultrasound, National Conference on the Management of Ovarian Cysts
2009	Canadian Forum for the Earlier Detection and Diagnosis of Breast Cancer
2010	Center for Disease Control & Prevention, Annual Cancer Registry Meeting, Atlanta, Georgia
2010	6th Annual HMO Research Network conference, Emerging Frontier in Healthcare & Research Delivery, Austin, Texas
2010	National Council on Radiation Protection (NCRP), Communication of Radiation Benefits and Risks in Decision Making
2010	National Cancer Institute, Board of Scientific Advisors, Bethesda, Maryland
2010	American Statistical Association Conference on Radiation Health, Annapolis, Maryland
2010	Breast Cancer Surveillance Consortium Annual Meeting, Washington, D.C.
2010	Kaiser Permanente: National Radiology Leadership Group, held at the RSNA, Chicago, IL
2011	Cleveland Clinic, Health Care Quality Innovation, Cleveland, Ohio
2011	Auntminnie.com, Live webex Conference RADEXPO 2011

2011	University of New Mexico, Visiting Professor, External Reviewer, Resident Research Day
2011	Oregon Health Sciences University, Department of Emergency Medicine, Grand Rounds
2012	Society for Imaging Informatics for Medicine, San Francisco, CA
2012	Grand Rounds, Department of Emergency Medicine RI Hospital (Brown University), Providence, RI
2012	Society for Imaging Informatics In Medicine, Los Angeles, CA
2012	PharmMed OUT, Georgetown University, Washington, DC
2012	Agency for Healthcare Research and Quality, Rockville, MD
2012	PharmMed OUT, Georgetown University, Washington
2012	Radiology Society of North America, Mock Trial Focused on Radiation and Need to Communicate, Chicago, IL
2012	Grand Rounds, University of Pennsylvania, Philadelphia, PA
2013	Radiology Society of North America (RSNA), Controversies Session, "CT Radiation and Risk: How Certain Are We of the Uncertainty?"
2013	American Cancer Society, Doc Talk Lecture Series, Oakland, CA
2013	Association of University Radiologists (AUR), RAHSR Session: "Comparative Effectiveness and Patient-centered Outcomes Research", Los Angeles, CA
2013	UCSF Otolaryngology Conference, San Francisco, CA
2014	Cancer.net Podcast, "CT Scans and Cancer Risk", Available Online at http://www.cancer.net/blog/2014-10/ct-scans-and-cancer-risk
2014	Oregon Chapter, American College of Emergency Physicians, Portland, Oregon
2015	Women in Government Foundation (non-profit, non-partisan organization of all U.S. female state legislators) Diagnostic Imaging. Increasing Its Effectiveness and Safety, at 16th Annual Southern & Eastern Regional Conference, Charleston S Carolina
2016	Lindeberger Cancer Center, University of North Carolina, Chappil Hill NC, Radiation From Medical Imaging: A Hidden Epidemic

2016	Current CT doses from a Computed Tomography Dose Registry, presented at the Conference on Radiation in Health, Radiation Research Society, Kona, HI	
2016	Current Exposure to Computed Tomography Imaging in US Integrated Health Care Systems, presented at the Conference on Radiation in Health by the Radiation Research Society, Kona, HI	
2017	Current CT doses from a Computed Tomography Dose Registry in Pediatric Patients, Presented at the American Academy of Pediatrics Annual Meeting, San Francisco, CA	
2017	Center for Diagnostic Imaging Quality Institute Council of Medical Directors, Scottsdale, AZ Keynote: Radiation from Medical Imaging	keynote
2017	The Leap Frog Group Pediatric Computed Tomography Radiation Dose	
2017	PCORI Advisory Panel on Communication and Dissemination Research Presentation UCSF CT Radiation Dose Registry to Ensure a Patient-Centered Approach for Imaging	
2017	American Urological Association (AUA) Quality Improvement Summit, Baltimore Maryland Keynote Address. Imaging Wisely: Improving the Value of Medical Imaging	keynote
2018	Society of Radiologists in Ultrasound, 28th Annual Meeting, Thyroid Imaging, San Diego, CA	
2018	National VA Radiology Meeting, Keynote: Improving Radiation Doses for CT, Miami Fl	
2019	Radiation Exposure and Breast Cancer. Presented to the California Breast Cancer Primary Prevention Plan	
2019	Radiation and Medical Imaging. Keynote, Radiology Partners National Pratice Leadership Summit, Arizona	
2021	Radiology Society of North America (RSNA), Essentials Course: Chasing the Holy Grail: Reducing Radiation Dose and Improving Image Quality, Chicago, IL	
2021	Radiology Society of North America (RSNA), Hot Topic: Controversies in Imaging Utilization, Chicago, IL	
2021	Radiology Society of North America (RSNA), Learning Health Care System: An Introduction for Radiologists to the Learning Healthcare System: Pragmatic Trials- Yes, We Can Randomize!, Chicago, IL	

2021	Radiology Society of North America (RSNA), Medical Physics Section: □Protocol Optimization for Low Dose CT□, Chicago, IL	
2021	Society of Radiologists in Ultrasound (SRU) Annual Meeting, Invited plenary talk: "Post-menopausal stripe thickness and need for Doppler of the EMS," Online	
2021	National Academy of Medine, Working Group, "Developing a Long-Term Strategy for Low-Dose Radiation Research in the United States Medical Perspectives," Teleconference	

INVITED PRESENTATIONS - REGIONAL AND OTHER INVITED PRESENTATIONS

2000	Kaiser Permanente Department of Genetics	
2001	San Francisco State University	
2001	Department of Medicine Grand Rounds, UCSF, San Francisco General Hospital	
2001	American College of Obstetrics and Gynecology, San Francisco, CA	
2001	Primary Care Medicine, Aspen, CO	Speaker
2001	UCSF Continuing Medical Education: Diagnostic Imaging in the Chest	Speaker
2001	UCSF Continuing Medical Education: Diagnostic Imaging in Women's Health	Speaker
2001	UCSF Continuing Medical Education: Diagnostic Imaging for Common Clinical Problems	Speaker
2001	UCSF Continuing Medical Education: Management of the Hospitalized Patient, San Francisco, CA	Speaker
2001	UCSF Continuing Medical Education: Controversies in Women's Health	Speaker
2001	MRI & Ultrasound, Lake Tahoe, CA	Speaker
2001	Intrauterine Growth Restriction, Lake Tahoe, CA	Speaker
2001	Evaluating the Uterus, Lake Tahoe, CA	Speaker
2002	Obstetrics and Gynecology Update, San Francisco, CA	Speaker
2002	17th Annual Primary Care Medicine, Aspen, CO	Speaker
2002	Diagnostic Imaging for Cancer Screening, Aspen, CO	Speaker
2002	10th Annual Controversies in Women's Health, San Francisco, CA	Speaker

2002	UCSF Continuing Medical Education: Diagnostic Imaging in Women's Health, San Francisco, CA	Speaker
2002	Diagnostic Imaging: Evaluation of the Uterus in Postmenopausal Bleeding, Maui, HI	Speaker
2002	Diagnostic Intrauterine Growth Restriction	Speaker
2002	Evidence-Based Radiology: What Does It Mean? Why is it Important? Maui, HI	Speaker
2002	UCSF Continuing Medical Education: OB/GYN and Abdominal Ultrasound: Soft Ultrasound Markers, San Francisco, CA	Speaker
2002	Breast Oncology Program, Comprehensive Cancer Center, UCSF	
2003	Primary Care Medicine, Maui, HI	Speaker
2003	Diagnostic Imaging in Clinical Practice, Maui, HI	Speaker
2003	11th Annual Controversies in Women's Health, San Francisco, CA	Speaker
2003	UCSF Continuing Medical Education: Diagnostic Imaging for Disease Prevention, San Francisco, CA	Speaker
2003	UCSF Continuing Medical Education: 46th Annual Diagnostic Radiology Postgraduate Course	Speaker
2003	UCSF Continuing Medical Education: OB/GYN and Abdominal Ultrasound, Soft Ultrasound Markers: The Results of the California AFP Study	Speaker
2003	MRI and Ultrasound by the Lake, Evaluation of the Uterus in Postmenopausal Bleeding Diagnostic Intrauterine Growth Restriction, Lake Tahoe, CA	Speaker
2003	Obstetrics and Gynecology Grand Rounds, UCSF	
2004	Women's Imaging, Does Practice Make Perfect: The Relationship Between Volume and Accuracy of Mammography, Sonoma, CA	Speaker
2004	Primary Care Medicine, Aspen, CO 2004 Diagnostic Imaging in Women's Health, Aspen, CO	Speaker
2004	Primary Care Medicine, Maui, HI 2004 Diagnostic Imaging in Women's Health, Mau, HI	Speaker
2004	Diagnostic Imaging in Clinical Practice, Mau, HI	Speaker
2004	UCSF Continuing Medical Education: Diagnostic Imaging in Clinical Practice, San Francisco, CA	Speaker
2004	Racial Disparity: Avon-sponsored Symposium, UCSF	

2004	Quality of Breast Cancer Care: Symposium , UCSF, San Francisco, CA	
2005	Sisters Network San Francisco	
2005	Stanford University, Department of Health Research and Policy, Division of Epidemiology	
2005	Obstetrical and Gynecologic Sonography, Postmenopausal Vaginal Bleeding, San Francisco, CA	Speaker
2005	Radiology Spring Training, Scottsdale, AZ	Speaker
2005	Evidenced Based Radiology: What Does It Mean And Why Should You Care, Scottsdale, Arizona	Speaker
2005	Imaging Evaluation Of Vaginal Bleeding, Scottsdale, Arizona	Speaker
2005	Pelvis Masses: What□s Normal, What□s Not, Scottsdale, Arizona	Speaker
2005	Physician Predictors of Mammographic Accuracy, Scottsdale, Arizona	Speaker
2005	Screening For Lung Cancer, Scottsdale, Arizona	Speaker
2005	Update in Imaging Including Screening	Speaker
2005	Screening Mammography: Does Practice Make Perfect	Speaker
2005	Imaging Evaluation Of Vaginal Bleeding	Speaker
2005	Interpreting the Medical Literature Made Easy	Speaker
2006	Lunch and Learn: San Francisco Community Outreach Educational Program, UCSF	
2006	Bay Area Health Care and Quality Outcomes, UCSF, San Francisco, CA	
2006	UCSF Continuing Medical Education: Controversies in Women's Health	Speaker
2006	UCSF Continuing Medical Education: Controversies in Breast Cancer Screening and Diagnosis	Speaker
2006	Cutting Edge Radiology, Diagnosis and Intervention, Vancouver, Canada	Speaker
2006	Evidenced Based Radiology: What Does It Mean And Why Should You Care	Speaker
2006	Screening Mammography: Does Practice Make Perfect	Speaker
2006	Pelvis Masses: What□s Normal, What□s Not	Speaker

2006	Imaging Evaluation Of Vaginal Bleeding Prenatal Diagnosis Of Down Syndrome: What You Need To Know, Vancouver, Canada	Speaker
2006	Educational Symposia	Speaker
2007	California Breast Cancer Research Symposium, Los Angeles, CA	
2008	UCSF Continuing Medical Education: Primary Care Medicine	Speaker
2008	UCSF Continuing Medical Education: Diagnostic Imaging in Women's Health	Speaker
2008	UCSF Continuing Medical Education: Radiation from Medical Imaging: A Silent Epidemic	Speaker
2008	UCSF Continuing Medical Education: Obstetrical/Gynecological and Abdominal Sonography Update, Prenatal Screening: What Not to Pay Attention To	Speaker
2009	UCSF Continuing Medical Education: Primary Care Medicine	Speaker
2009	UCSF Continuing Medical Education: Evaluation of Common Symptoms in Women	Speaker
2009	UCSF Continuing Medical Education: Radiation from Medical Imaging: A Silent Epidemic	Speaker
2009	UCSF Continuing Medical Education: Obstetrical/Gynecological and Abdominal Sonography Update, Prenatal Screening: What Not to Pay Attention To	Speaker
2010	Bay Area Clinical Research Symposium , Plenary Speaker, San Francisco CA	
2011	Department of Medicine Grand Rounds, UCSF, Moffitt, San Francisco, CA	
2011	Department of Medicine, Grand Rounds, San Francisco General Hospital, San Francisco, CA	
2011	Department of Urology Grand Rounds, UCSF, San Francisco, CA	
2011	Radiation Associated with Medical Imaging, Department of Radiology Grand Rounds, UCSF, San Francisco, CA	
2011	Eden Hospital, Department of Medicine Grand Rounds, Alameda, CA	
2011	Stanford Hospital, Department of Medicine, Grand Rounds, Palo Alto, CA	
2011	Kaiser Permanente Medical Center, Multidepartmental Grand Rounds, San Francisco, CA	

2011	Institute for Health Policy Studies, San Francisco, CA. Lecture entitled "Is Medical Imaging Harmful to Health: Opportunities to Influence Health Policy" Featured on UCTV http://www.uctv.tv/search_details.aspx?showid=21580	
2011	STONE: RCT of US versus CT for Patients in the CT with Suspected Urolithiasis, San Francisco, CA (8.75)	Course Director
2011	Primary Care Medicine, Principles & Practice, San Francisco, CA	Keynote Lecture
2011	39th Annual Advances in Internal Department of Medicine, San Francisco, CA	Keynote Lecture
2011	Controversies in Women's Health, Department of Medicine, San Francisco, CA	Keynote Lecture
2012	Grand Rounds, Kaiser Permanente Medical Center, San Francisco, CA	
2012	Grand Rounds, Kaiser Permanente Medical Center, Oakland, CA	
2012	Grand Rounds, Department of Emergency Medicine, Massachusetts General Hospital, Boston, MA	
2012	Grand Rounds, Department of Emergency Medicine Beth Israel Hospital, Boston, MA	
2012	Presentation, UC Office of the President, Focused on Quality Improvement and Technology, Oakland, CA	
2012	Grand Rounds, Department of Radiation Oncology, UCSF, San Francisco, CA	
2012	Grand Rounds, Southern CA Kaiser Radiology Chiefs	
2012	Thyroid Nodules: What Does the Evidence Really Tell Us, Maui, HI	Speaker
2012	Radiation for CT: Strategies for Meeting Expectations and Regulatory Compliance, Maui, HI	Speaker
2013	UCSF Continuing Medical Education: Radiation from Medical Imaging: A Hidden Epidemic	Speaker
2013	UCSF Continuing Medical Education: Otolaryngology Update	Speaker
2014	American College of Emergency Physicians, Oregon Chapter (O.C.E.P)	
2014	Endocrine Grand Rounds, Division of Endocrinology and Metabolism & the Diabetes and Endocrinology Research Center, UCSF, San Francisco, CA: "Risk of Thyroid Cancer Based on Thyroid Ultrasound Imaging Characteristics"	

2014	Radiology Resident Lecture Series, Department of Radiology, UCSF, San Francisco, CA: "Tracking and Monitoring CT Dose and Its Impact: Across the University of California Medical Centers"	
2014	UCSF, Endocrine Grand Rounds, San Francisco, CA	
2015	California Society of Radiology Technologists, Annual Meeting, San Francisco, CA Keynote Address. Radiation from CT: A Hidden Epidemic. Strategies to minimize doses: What technologists can do?	
2016	Society of Radiology in Ultrasound, Annual Meeting, Baltimore Maryland. Risk of Thyroid Cancer Based on Thyroid Ultrasound Imaging Characteristics	
2016	UCSF, Breast Oncology Program, Radiation from Medical Imaging: A Hidden Epidemic and Approaches for Improving.	
2016	UCSF Mini-Medical School Radiation Safety and Medical Imaging	
2017	University of California, Fetal Treatment Consortium: Share Our Experience with the University of California Dose Optimization and Standardized Endeavor (UC DOSE)	
2017	Breast Cancer Prevention Partners Ionizing Radiation and Cancer	
2017	University of California Davis, Radiology Grand Rounds, Radiation from Medical Imaging; A Hidden Epidemic	
2017	UCSF, Stand Up For Science; Panel Discussant	
2017	UCSF Practical Body Imaging, Kona Hawaii. 5 lectures	Lecturer
2019	Radiation Associated with Medical Imaging and Breast Cancer. Presented as part of the Study Group Series to inform The Breast Cancer Primary Prevention Plan for the State of California, California Breast Cancer Research Program	
2020	Bay Area Clinical Research Symposium Keynote Address: "A Medical Triumph Fostering a Silent Epidemic"	
2021	UCSF Pediatric Grand Rounds, "Computed Tomography: A Medical Triumph Fostering a Silent Epidemic"	
2022	UCSF Epidemiology Grand Rounds, "Computed Tomography: A Medical Triumph Fostering a Silent Epidemic"	
2023	UCSF Course, UCSF Radiation Safety in Computed Tomography Virtual Symposium 2023, "Radiation from Medical Imaging, A Hidden Epidemic"	Keynote Lecture

2023	UCSF Course, UCSF Radiation Safety in Computed Tomography Virtual Symposium 2023, Best Practices of Organizations with Optimized Dose.
2023	UCSF Course, UCSF Radiation Safety in Computed Tomography Virtual Symposium 2023, The Use of Multiphase Scanning, Do Less
2023	UCSF Course, UCSF Radiation Safety in Computed Tomography Virtual Symposium 2023, Routine Abdomen CT-How Often are Best Practices Followed
2023	UCSF Course, UCSF Radiation Safety in Computed Tomography Virtual Symposium 2023,Strategies for Dose Optimization: Views from Health Care Systems
2023	

GOVERNMENT AND OTHER PROFESSIONAL SERVICE

2002 - 2003	Centers for Disease Control and Prevention, National Breast & Early Detection Program	Planning Committee
2003 - 2010	National Cancer Institute, Physician Data Query (PDQ)	Committee Member
2004 - 2005	Center for Disease Control and Prevention, CDC National Breast and Cervical Cancer Early Detection Program, Committee on Assessment of Covered Benefits	Expert Panelist
2007 - 2010	California Health Benefits Review Program (CHBRP)	Content Expert
2008 - 2010	Center for Scientific Review (CSR), National Institute of Heath (NIH), Health Services Organization and Delivery (HSOD)	Study Section Member
2010 - 2010	Congressional Hearing, US House of Representatives, Energy and Commerce Committee, Subcommittee on Health. Medical Radiation: An Overview of the Issues	Expert Witness
2010 - 2010	Food and Drug Administration, Center for Devices & Radiological Health, National Meeting Focus on Radiation Safety	Presenter
2012 - 2013	The Joint Commission, Diagnostic Ionizing Radiation and Magnetic Resonance	Expert Panel Committee
2012 - 2012	CDC Cancer Prevention Workshop: in-person meeting, October 17-18, 2012	Committee Member

2012 - 2012	Congressional Hearing, US House of Representatives, Energy and Commerce Committee, Subcommittee on Health: Hearing was examining the appropriateness of standard form Medical Imaging, and Radiation Therapy Technologist. CARE Bill	Expert Witness
2013 - 2013	Government Accountability Office Report: Medicare Imaging Accreditation Establishing Minimum National Standards and an Oversight Framework Would Help Ensure Quality and Safety of Advanced Diagnostic Imaging Services, May 2013	Contributor
2014 - 2014	International Atomic Energy Agency (IAEA) United Nations General Assembly and Security Council. Special Committee Considering Impact of Low Dose Radiation	
2015 - 2021	Council of Distinguished Investigators of the Academy of Radiology Research	

UNIVERSITY AND PUBLIC SERVICE

SERVICE ACTIVITIES SUMMARY

There are several activities to which Dr. Smith-Bindman has contributed. For seven years she participated in the NCI sponsored Physicians Data Query (PDQ), an NCI committee charged with presenting evidenced based, on-line, widely accessible and widely disseminated guidelines relating to cancer screening and diagnosis.

She participated in several activities related to breast cancer screening including acting as a reviewer for the CDC on assessing the guidelines for the National Breast and Cervical Cancer Detection Program, participating in coverage decisions for the California Medicare program by acting as reviewer and content expert for the CA Health Benefits Review Program analyzing several bills before the state legislature that would expand breast cancer screening to include MRI.

She has contributed to several National Academy of Medicine Reports. She has participated in several community projects, such as acting on the board of an African American breast cancer advocacy group, and as a consultant to the Metropolitan Breast Cancer Task Force, charged with improving breast cancer mortality rates and racial disparities.

During the last ten years She has been very active in local, California, national and international efforts around improving radiation safety, including invited presentations to the FDA, testifying before the US Congress on two occasions, working with innumerable societies and government organizations on guidelines and submitting five endorsed quality measures on radiation safety to the National Quality Forum. Three of these measures were developed through a cooperative agreement with CMS, and she has worked closely with diverse stakeholders to see these measures to inclusion in national regulation to ensure improvement in radiation safety.

Her involvement in service activities within the University have focused on increasing the quality and quantity of translational research through participation in several University-wide

task forces. Dr. Smith-Bindman serves on several Medical Center Committees, focusing on improved oversight and stewardship around radiation, and projects to improve the efficiency and effectiveness with CT. She also has served for many years on the University Conflicts of Interest Committee.

In the Department of Epidemiology and Biostatistics, she was a member of a department wide task force focused on improving undergraduate education.

UNIVERSITY SERVICE
UC SYSTEM AND MULTI-CAMPUS SERVICE

2003 - 2003	Blueprint for Regional Excellence in Breast Cancer Care	Committee Member
2007 - 2010	University of California, Office of the President, California Health Benefits Review Program (CHBRP)	Content Expert, Review of California Pending Legislation
2011 - 2013	Standardization and Optimization of Computed Tomography Patient Radiation Dose Across UC Medical Centers, funded through UC Center for Health Quality & Innovation Program (CHQI)	Committee Chair
2015 - 2020	Member, University of California Qualified Provider Led Entity Steering Committee (QPLE) Member, Imaging Appropriate Use Committee	

UCSF CAMPUSWIDE

2003 - 2003	UCSF Hospital Exceptional Physician Award	Committee Co-Chair
2006 - 2007	Pathways Clinical and Translational Research	Subcommittee
2008 - 2010	Pathways To Discovery, Clinical and Translational Research Pathway	Advisory Council
2009 - 2021	Radiation Safety Committee	Committee Member
2012 - 2014	UCSF Medical Center for Health Care Value	Committee Member
2014 - 2015	UCSF Clinical Enterprise Strategic Plan Implementation Committee for Continuous Process Improvement (CPI)	Committee Member
2015 - 2017	UCSF Clinical Enterprise Utilization Management Committee	Committee Member
2012 - 2024	UCSF Conflict of Interest Advisory Committee (COIAC)	Committee Member

SCHOOL OF MEDICINE

2002 - 2002	Dean's Leadership Retreat, Santa Cruz, CA	Participant

2003 - 2003	Task Force, Future of UCSF and Mission Bay	Steering Committee Member
2003 - 2004	Task Force, Physician Scientist Program Clinic-Based	Steering Committee Member
2005 - 2005	Dean's Leadership Retreat, Santa Cruz, CA	
2003 - 2005	School of Medicine	Faculty Council
2008 - 2010	UCSF Pathways to Discovery, Clinical and Translational Research	Advisory Council
2007 - 2010	University of California, Office of the President, CA Health Benefits Review Program	
2012 - 2015	UCSF Medical Center, Center for Health Care Value	
2013 - 2020	UCSF School of Medicine, Conflict of Interest Advisory Committee	
2014 - 2016	UCSF Clinical Enterprise, Strategic Plan, Committee for Continuous Process Improvement	
2015 - 2019	UCSF Clinical Enterprise, Utilization Management Committee	
2019 - 2022	UCSF Division of Palliative Medicine Associate Chief for Research Search Committee	
2020 - 2022	UCSF Division of Palliative Medicine Faculty Researcher Search Committee	

DEPARTMENTAL SERVICE

2001 - 2004	Department of Medicine Faculty Recruitment Committee	Member
2001 - 2004	Department of Radiation Oncology Faculty Recruitment Committee	Member
2005 - 2005	Department of Radiology Seminars and Presentation Committee	Member
2005 - 2008	Department of Radiology Annual Imaging Research Symposium Abstract Review Committee	Member
2005 - 2009	Department of Radiology SEED Grant Review Committee	Member
2009 - 2021	Department of Radiology, Radiation Safety Committee	Member
2012 - 2014	Department of Radiology Maintenance of Certification Committee	Member
2012 - 2014	Department of Radiology, Maintenance of Certification Committee	Member

2016 - 2020	Department of Radiology Development Committee	Member
2020 - 2021	Department of Radiology Quality and Safety Committee	Member
2020 - 2021	Department of Radiology Health Equity Committee	Member
2020 - 2022	Department of Radiology Medical Physicist Faculty Search Committee	Member
2022 - 2023	Department of Epidemiology and Biostatistics, Task Force, Undergraduate Medical Education	Member

COMMUNITY AND PUBLIC SERVICE

2003 - 2007	San Francisco SISTERS, African American Breast Cancer Advocacy Group	Board Member
2008 - 2008	Metropolitan Chicago Breast Cancer Task Force, Chicago IL	Unpaid Consultant
2011 - 2014	National Quality Form, National Voluntary Consensus Standard for Patient Safety. Measure entitled "UCSF CT Radiation Dose Patient Safety Measure PSM-044 endorsed	Measure Developer
2015 - 2015	National Quality Form, Pediatric Measures. Measure Entitled: "Pediatric Computed Tomography Radiation Dose." Measure Endorsed.	Measure Developer
2017 - 2017	Leapfrog Voluntary Consultant to Coordinate Implementation of National Quality Form Pediatric Safety Measure.	Voluntary Consultant
2019 - 2019	Presenter, Contributor, External Peer Reviewer of Final Report, California Breast Cancer Primary Prevention Plan, California Breast Cancer Research Program	
2020 - 2023	Tomales Bay Watershed Foundation	Board Member
2020 - 2023	San Francisco New Deal, a non-profit focused on serving San Francisco s vulnerable populations and supporting restaurants during Covid-19; and supporting businesses sustainability. Led successful application for two SF government contracts.	Development Committee Member

CONTRIBUTIONS TO DIVERSITY

CONTRIBUTIONS TO DIVERSITY Contributions to Diversity, Equity & Inclusion Guidance

I have tried to increase my understanding of the structural nature of racism and approaches for becoming antiracist. I have read as many books as possible over the last several years about the foundation of structural racism. This past year I participated in training by REI (Racial Equity Institute) and the Groundwater Institute focused on leadership development. The focus of the Groundwater institute is to helps leaders communicate, translate, and apply our racial

equity analysis for strategic action to impact change. I learned of the program through my husband who previously participated in their leadership training and found it extremely informative. (https://racialequityinstitute.org/groundwater-institute/)

TEACHING AND MENTORING

TEACHING SUMMARY

Dr. Smith-Bindman has become involved in Teaching in the Department of Epidemiology and Biostatistics. She is a small group leader in the fourth year Designing Clinical Research Class; and has led four sections in the First year Epidemiology and Biostatistics Course.

FORMAL TEACHING

	Academic Yr	Course No. & Title	Teaching Contribution	School	Class Size
	2002 - 2005	Epidemiology and Biostatistics, Medical Student Required Class	Section Leader		20
	2005 - 2005	Introduction to Diagnostic Testing	Lecturer		18
	2007 - 2008	Clinical Performance and Health Outcome Measurement, Epidemiology and Biostatistics 211	Faculty Lecturer		20
	2011 - 2012	Epidemiology 245, Translating Evidence into Practice: Theory and Design	Lecturer		30
	2010 - 2014	Epi 249, Framing Research to Influence Policy	Lecturer		25
	2013 - 2014	"Translating Evidence Into Policy", a part of UCSF's Masters in Clinical Research Program, Department of Epidemiology & Biostatistics, UCSF	Lecturer		
	2014 - present	UCSF Resident Didactic Lectures	Lecturer		

	Academic Yr	Course No. & Title	Teaching Contribution	School	Class Size
	2017 - 2017	UCSF Practical Body Imaging, Kona Hawaii. 5 lectures	Lecturer		
	2021 - 2022	UCSF Epidemiology, Biostatistics and Population Sciences (EBPS), led four sections	Section leader		15
	2022 - 2023	UCSF Medical Student 4th Year Class, Designing Clinical Research (DCR). Led all sections (n=6) and review of final proposal	Section leader	Medicine	15

MENTORING SUMMARY
Dr. Smith-Bindman mentors trainees in clinical research. Current primary mentees during 2022 include Malini Mahendra, UCSF faculty member in Pediatrics applying for a K award, and several Radiation Medical Physics grad students (Cameron Kofler, Trung Tran)

PREDOCTORAL STUDENTS SUPERVISED OR MENTORED

Dates	Name	Program or School	Mentor Type	Role	Current Position
2004 - 2005	Christopher Kagay	UCSF Medical School		Research Advisor	Radiologist
2005 - 2006	Alexander Ding	UCB/ UCSF Joint MD/MPH		Research Advisor	Radiologist
2005 - 2008	Aruna Venkatesan	UCSF Medical School		Research Advisor	Obstetrician Gynecologist
2006 - 2007	Emma Dinkelspiel	Urban High School		Research Advisor	Lawyer, Legal Aid, San Francisco
2010 - 2014	Pratik Mehta	UC Berkeley		Research Advisor	Physician

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Dates	Name	Program or School	Mentor Type	Role	Current Position
2011 - 2013	Jillian Keegan	Lick Wilmerding High School		Research Advisor	Medical School, Mount Sinai
2012 - 2013	Jessica Zhang	UC Berkeley		Research Advisor	Medical School
2014 - 2014	A. Fraser	University High	Research/Scholarly Mentor,Project Mentor	Research Advisor	Works in Public Service, San Francisco
2019 - 2021	A. Alejandrez Cisneros	UCSF Medical School	Research/Scholarly Mentor,Project Mentor	Research Advisor	Medical School
2020 - 2023	Cameron Kofler	University of Florida, PhD Program, Medical Physicist	Research/Scholarly Mentor,Project Mentor	Research Advisor, PhD Advisor and Committee Member	Clinical Fellow, University of Chicago
2020 - 2023	Emily Marlow	UC Davis, Epidemiology PhD Program	Research/Scholarly Mentor,Project Mentor	Research Advisor, PhD Advisor, Committee Member	Post Doc, American Cancer Society
2020 - 2023	Truong Tran	University of Florida, PhD Program, Medical Physics	Research/Scholarly Mentor,Project Mentor	Research Advisor, PhD Advisor	Physics Program
2022 - 2023	Gabriela Steiner	UCSF Medical School	Research/Scholarly Mentor,Career Mentor	Research/Career Mentor	Medical School
2023 - 2024	Megan Casey	UCSF Medical School and Masters Student UCSF	Research/Scholarly Mentor	Research Mentor, Committee member	

POSTDOCTORAL FELLOWS AND RESIDENTS MENTORED

Dates	Name	Fellow	Mentor Role	Faculty Role	Current Position
1998 - 2000	Mariana Copanigro	UCSF Radiology Resident and Fellow		Research Advisor	Radiologist
1998 - 2000	Nina Vincoff	UCSF Radiology Resident and Fellow		Research Advisor	Radiologist
2003 - 2004	Erica Weiss	UCSF Obstetrics & Gynecology		Research Advisor	Obstetrician Gynecologist
2003 - 2005	Kristen Schueler	UCSF RORL Research Fellow		Research Advisor	Radiologist
2003 - 2005	David Haggstrom	UCSF Internal Medicine Fellow, Masters Student		Research Advisor	Indiana University, Faculty, Department of Medicine
2005 - 2006	Kristen Reid	UCSF General Internal Medicine Fellow		Research Advisor	Emory Univeristy / Grady Hospital, Faculty, Medicine
2005 - 2005	A. Jensen	PhD Student, Copenhagen		Research Advisor	Faculty
2005 - 2006	Brian Ching	UCSF Radiology Fellow		Research Advisor	Radiologist
2005 - 2006	Amy Cole	UCSF Radiology Fellow		Research Advisor	Radiology, Kaiser Permanente

Dates	Name	Fellow	Mentor Role	Faculty Role	Current Position
2005 - 2007	Lauren Goldman	UCSF Internal Medicine Fellow, Masters Student		Research Advisor	UCSF Department of Medicine
2006 - 2010	Jafi Lipson	UCSF Radiology Resident, UCSF Radiology T32 Scholar		Research Advisor	Faculty, Stanford University
2007 - 2008	Joseph Stengel,	UCSF Radiology Fellow			Radiologist
2007 - 2008	Agiua Heath	UCSF RORL Research Fellow		Research Advisor	Private Practice
2007 - 2009	Richard Cho	UCSF Radiology Fellow		Research Advisor	Private Practice, Los Angeles, CA
2007 - 2009	Dorra Sellami	UCSF Radiology Resident/Radiology Fellow		Research Advisor	Radiology Private Practice
2008 - 2009	Amita Kamath	UCSF Radiology Resident UCSF T32 Scholar		Research Advisor	Faculty, Radiologist, NYU
2009 - 2010	Jin Ching	UCSF Maternal Medicine Fellow		Research Advisor	Radiologist
2009 - 2011	Natasha Brasic	UCSF Radiology Fellow		Research Advisor	Radiologist
2010 - 2011	Divya Sridhar	UCSF Radiology Resident		Research Advisor	Radiologist

Dates	Name	Fellow	Mentor Role	Faculty Role	Current Position
2010 - 2012	Paulette Lebda	UCSF Radiology Fellow		Research Advisor	Radiologist
2010 - 2013	Ingrid Burger	UCSF Radiology Resident		Research Advisor	Radiologist
2010 - 2013	Ginger Merry	UCSF Radiology Resident		Research Advisor	Radiologist
2011 - 2014	John Mongan	UCSF Radiology Resident, UCSF Radiology Fellow		Research Advisor	UCSF Faculty
2013 - 2014	Stephanie Hou	UCSF Radiology Resident		Research Advisor	UCSF
2013 - 2014	Cindy Lee	UCSF Radiology Fellow		Research Advisor	Radiologist
2013 - 2014	Tara Morgan	UCSF Radiology Fellow and UCSF Radiology attending		Research Advisor	UCSF Faculty
2013 - 2015	Lindsay A. Hampson	UCSF Urology Resident, One Year of Dedicated Research		Research Advisor	UCSF Faculty
2013 - 2015	Vignesh Arasu	UCSF Radiology Resident		Research Advisor	Radiologist
2013 - 2015	Nancy Benedetti	UCSF Radiology Resident		Research Advisor	Radiologist

Prepared: March 9, 2024

Dates	Name	Fellow	Mentor Role	Faculty Role	Current Position
2014 - 2015	Bianca Carpenter	UCSF Radiology Fellow		Research Advisor	Radiologist
2014 - 2015	Janice Hsu	UCSF Radiology Fellow		Research Advisor	Radiologist
2014 - 2018	Yifei Wang	UC Davis, PhD Biostatistics		Research Advisor	UCSF Faculty
2014 - 2019	Joshua Demb	UCSF, PhD Epidemiology		Research Advisor	UCSD, Research Scientist
2015 - 2018	Emily Marshall	University of Florida, PhD Medical Physics		Research Advisor	Lurie Childrens Hospital, Medical Physicist
2017 - 2021	Emily Marlow	UC Davis, PhD Epidemiology		Research Advisor	American Cancer Society
2018 - 2021	Calyani Ganesan	Nephrology Fellow		Research Advisor	Stanford
2018 - 2020	Yoon-Jin Kim	Radiology Resident		Research Advisor	UCSF Fellow
2018 - 2022	Truong Tran	University of Florida, PhD Medical Physics		Research Advisor	
2018 - 2022	Cameroon Kofler	University of Florida, PhD Medical Physics		Research Advisor	PhD Candidate
2019 - 2021	Denise Oldenburg	Visting Radiology Resident		Research Advisor	University of Essen
2019 - 2022	Sean Woolen	Radiology Fellow		Research Advisor	UCSF Abdominal Imaging Attending

Dates	Name	Fellow	Mentor Role	Faculty Role	Current Position
2021 - 2022	Xiao Wu	UCSF Radiology Resident		Research Advisor	

FACULTY MENTORING

Dates	Name	Position while Mentored	Mentor Type	Mentoring Role	Current Position
2002 - 2005	John Shepherd,MD	UCSF Emergency Medicine		Research Advisor	UCSF Faculty
2004 - 2005	Elaina Curtis, MD	UCSF Visiting Fellow		Research Advisor	Faculty, University of Auckland
2005 - 2006	John Stein, MD	UCSF Emergency Medicine		Research Advisor	Associate Professor, UCSF
2005 - 2006	Max Wintermark, MD	UCSF Radiology		Research Advisor	Section Head, Neuroradiology Stanford
2007 - 2014	Lauren Goldman, MD	UCSF Medicine		Research Advisor	Professor, UCSF
2008 - 2011	Larry Rand, MD	UCSF Maternal Medicine		Research Advisor	Professor, OBGYN, UCSF
2008 - 2014	Antonio Westphalen, MD	UCSF Radiology, KL2		Research Advisor	Section Head, Body Imaging University of Washington
2009 - 2018	Liina Poder, MD	UCSF Radiology		Research Advisor	Section Head, Ultrasound, UCSF
2010 - 2018	Ralph Wang, MD	UCSF Emergency Department Physician		Research Advisor	Professor, UCSF, Emergency Medicine

Dates	Name	Position while Mentored	Mentor Type	Mentoring Role	Current Position
2014 - 2018	John Mongan, MD	UCSF Radiology Resident, UCSF Radiology Fellow, Faculty		Research Advisor	Professor, UCSF
2014 - 2017	Cindy Lee, MD	UCSF Radiology Fellow		Research Advisor	Private Practice
2014 - 2017	Tara Morgan, MD	UCSF Radiology Fellow and UCSF Radiology Attending		Research Advisor	Associate Professor, UCSF
2014 - 2020	Maureen Kohi, MD	UCSF Radiology Faculty		Research Advisor	Department Chair, Radiology, UNC
2015 - 2018	Ben Franc, MD, PhD	UCSF Radiology, Nuclear Medicine		Research Advisor	Section Head, Nuclear Medicine, Stanford
2017 - 2020	Brian Haas, MD	UCSF Radiology Faculty		Research Advisor	Assistant Professor, UCSF
2018 - 2021	Matthew Bucknor	UCSF Radiology Faculty		Research Advisor	Professor, UCSF
2021 - 2023	Malini Mahendra	UCSF Pediatric Faculty	Research/Scholarly Mentor,Project Mentor	Research Advisor	Assistant Professor

VISITING FACULTY MENTORED

2005 - 2005 Allan Jensen University of Copenhagen

RESEARCH AND CREATIVE ACTIVITIES

RESEARCH AND CREATIVE ACTIVITIES SUMMARY

Dr. Smith-Bindman is a clinician scientist with expertise in health services research, epidemiology, outcomes research, comparative effectiveness research, and dissemination and implementation sciences focused on diagnostic imaging. Her research has focused on evaluating the quality, utilization, accuracy, predictive values and impact of diagnostic testing on patient health, and has quantified both the risks and benefits of medical imaging when used in different contexts and by different populations. She has spent been the principal investigator on numerous large federal grants and has collaborated with scientists from diverse medical specialty areas. Separate from her research activities, she has been actively involved in translating evidence into changes in practice and policy. She has informed policy leaders, practitioners and the public about the safety concerns surrounding the use of radiation in imaging by describing the issue in main stream media, testifying before the US Congress, and by advising the FDA, The Joint Commission, the International Atomic Energy Agency, the International Council on Radiation Protection and leading professional societies. She has also written quality measures focused on radiation safety, and her work has resulted in organizations which monitor health care quality to adopt measures of diagnostic imaging safety.

Two areas of focus are notable. First, she has published on the racial and ethnic differences in access and utilization of screening mammography and how that contributes to higher breast cancer mortality among African American women, and on factors that influence the quality and access to screening among vulnerable populations. Second, she has quantified the variation in radiation dose associated with medical imaging across patients and institutions, and quantified the impact of radiation, particularly from computed tomography, as an environmental carcinogen. She has conducted a successful, randomized controlled trial of strategies to lower doses.

She is currently writing quality measures through a cooperative agreement with CMS to be included in 2023 physician and hospital payment programs. The quality measures were supported by the National Quality Forum, were recommended for Rule Making as part of the 2022 Measure Application Partnership, and CMS is moving forward to include in their Physician and Hospital Payment Programs

Significant Publications

1. Smith-Bindman et al. Endovaginal ultrasound to evaluate endometrial abnormalities JAMA 1999;281:1693-4

Vaginal bleeding affects 7% of post-menopausal women, and historically women underwent invasive endometrial biopsy to exclude cancer. This meta-analytic review found that endovaginal ultrasound is an easily tolerated non-invasive test that is accurate for the diagnosis of cancer, so that most women can avoid biopsy. These results were integrated into clinical practice guidelines in the United States, Scotland, England, Germany, and Hong Kong. The publication was cited 895 times based on Google Scholar.

2. Smith-Bindman et al. Second-trimester ultrasound to detect fetuses with Down syndrome: a meta-analysis. JAMA. 2001: 285;1044-1055

This meta-analytic review suggests that the use of ultrasound for the detection of fetuses affected by Down syndrome may be associated with more harm than benefit, as it can lead to large numbers of unnecessary amniocenteses and subsequent fetal losses with little evidence of benefits. This article was accompanied by extensive media coverage (AP, Reuters, NY

Times), and impacted the use of ultrasound in prenatal diagnoses. The publication cited 196 times based on Web of Science.

3. Smith-Bindman et al. Comparison of screening mammography in the United States and the United Kingdom JAMA 2003;290: 2129-2137
This international comparison of screening mammography described 5.5 million mammograms obtained between 1996 to 1999 within three large-scale mammography registries or screening programs. Recall rates and open surgical biopsy rates were twice as high in the U.S. as in the U.K., although cancer rates were nearly identical. There was extensive media coverage (AP, Reuters, NY Times, Wall Street Journal, National Public Radio). The results were widely cited, and were included in the IOM Report, "Saving Women's Lives." The publication was cited 362 times based on Google Scholar.

4. Smith-Bindman et al. Physician Predictors of Mammographic Accuracy. J Natl Cancer Inst 2005:97;358-367
This retrospective analysis of the accuracy of mammographic screening among 208 U.S. physicians, who collectively interpreted 1.2 million mammograms, demonstrated large and unacceptable variation in theinterpretive abilities of radiologists; the sensitivity spanned 29% to 97%, while the false positive rate ranged from 1 to 29%. These findings were included in the Institute of Medicine's report on Mammography Quality Standards, regarding Enhancement of Interpretative Performance. The publication was cited 188 times based on Google Scholar.

5. Smith-Bindman et al. Does Utilization of Screening Mammography Explain Racial and Ethnic Differences in Breast Cancer? Ann Intern Med, 2006;144;541-51
This paper sought to disentangle whether biology or the use of screening was largely responsible for the known racial and ethnic differences in breast cancer. This study was unique in that detailed cancer information was available from tumor registries that were linked with detailed information regarding mammography utilization. Most of the racial and ethnic differences in breast cancer features were reduced or eliminated after accounting for the frequency of mammography screening suggesting reduced access to screening remains an important problem. The publication was cited 365 times based on Google Scholar.

6. Smith-Bindman et al. Radiation dose associated with common computed tomography examinations and the associated lifetime attributable risk of cancer. JAMA Internal Medicine 2009;169:2078-86
This paper documented the variation in doses associated with routine CT. The widespread media attention that this paper received contributed to active policy discussions questioning the need for greater standards and possible FDA oversight. I was invited to present the results at the FDA, at a Congressional Hearing sponsored by the Health Subcommittee of the Committee on Energy and Commerce, and innumerable professional society meetings, and submitted (and had endorsed) a measure of quality around CT imaging by the National Quality Forum. The publication was cited 2351 times based on Google Scholar.

7. Smith-Bindman R, Appendix F. Ionizing Radiation Exposure to the US Population, with a Focus on Radiation from Medical Imaging, included in Breast and the Environment: A Life Course Approach. The Institute of Medicine. 2012
The Komen Foundation commissioned the IOM report on environmental causes of breast cancer and. I was asked to summarize what is known about the harmful effects of ionizing radiation on breast cancer risks. The IOM concluded that ionizing radiation is one of the largest, and the most preventable causes of breast cancer. The publication was cited 71 times based on Google Scholar.

8. Miglioretti DL et al. Smith-Bindman senior author. The use of computed tomography in pediatrics and the associated radiation exposure and estimated cancer risk. JAMA Pediatr. 2013 ;167:700-707
Using a retrospective cohort design, this paper quantified the use of imaging among children within one of 7 large integrated health care systems including KP Northern California, KP Washington, KP Northwest, KP Georgia and KP Hawaii, quantified the radiation exposure associated with these examinations, and estimated the likely impact of improved standardization of the conduct of CT on the risks of cancer. The manuscript concluded that if the top outlying radiation exposures could be reduced to the average (a modest goal) that 40% of expected cancer could be eliminated. The publication was cited 995 times based on Google Scholar.

9. Smith-Bindman R, et al. Risk of Thyroid Cancer based on Thyroid Ultrasound Imaging Characteristic: Result of A Population Based-Study. JAMA Internal Medicine. 2013;173:1788-96
This retrospective observational study documented the risk of cancer associated with specific thyroid imaging findings. This is the first study that links a large cohort of patients with detailed imaging findings, with a comprehensive tumor registry to permit the quantification of the risk of cancer associated with specific findings. The results suggest that the number of biopsies can be reduced by up to 90%, with a relatively small impact on cancer detected. The results are being rapidly embraced by endocrinologists, surgeons and radiologists. The publication was cited 250 times based on Google Scholar.

10. Smith-Bindman et al Ultrasonography versus computed tomography for suspected nephrolithiasis Nephrolithiasis NEJM. 2014;371:1100-1110
This 15-center randomized comparative effectiveness study assessed whether ultrasound or CT should be the first imaging test in patients with suspected kidney stones. Emergency department patients with abdominal pain and suspected nephrolithiasis were randomly assigned to one of three arms for imaging: ultrasound performed by an emergency medicine physician, ultrasound provided by a radiologist, or computerized tomography (CT). No significant differences were observed over the next 6 months in rates of severe serious adverse events (SAEs), related SAEs, or total SAEs, or ED or hospital admission rates at 7 or 30 days; however, initial imaging with ultrasound was associated with lower 1 day and 6-month cumulative radiation exposures than initial imaging with CT. The publication was cited 473 times based on Google Scholar.

11. Smith-Bindman R, et al International Variation in Radiation Dose for Computed Tomography Examinations: Prospective Cohort Study. BMJ. 2019;364:K4931
This study used data describing one million CT scans submitted to the UCSF International CT Dose Registry and explored reasons for the variation in doses used for CT. The analysis found that it was not patient or machine factors that drove the large dose variation, but rather local preferences and choices. The paper is the first large multinational study to characterize and explore the reasons for dose variation. The publication was cited 63 times based on Google Scholar.

12. Smith-Bindman R, et al Trends in Use of Medical Imaging in US Health Care Systems and in Ontario, Canada JAMA 2019 322(9):843-856.
This retrospective study across 7 large integrated US health care systems including KP Northern California, KP Washington, KP Northwest, and KP Hawaii, and from Ontario Canada described current patterns of medical imaging. The paper documented ongoing growth in

nearly all imaging modalities despite widely held beliefs that growth in advanced imaging has subsided. The publication was cited 80 times based on Google Scholar.

13. Smith-Bindman R, et al Risk of Malignant Ovarian Cancer Based on Ultrasonography Findings in a Large Unselected Population. JAMA Intern Med. 2019 ; 179(1): 71-77
This large, retrospective population based study of ultrasound findings among enrolless in KP Washington documented the risk of cancer associated with specific findings, and provided evidence that ovarian cysts, no matter what their size, can be safely ignored. The results were rapidly incorporated into several national guidelines. The publication was cited 30 times based on Google Scholar.

14. Smith-Bindman, R., et al An assessment of two interventions for reducing radiation doses for computed tomography: A multicenter international clinical trial. JAMA Internal Med. 2020; 180:666-675.
This randomized clinical trial of two interventions to optimize radiation doses for CT across 100 imaging facilities found that providing feedback to institutions along size education and opportunities for sharing best practices results in meaningful dose reductions.

RESEARCH AWARDS - CURRENT

1.	PI		Smith-Bindman (PI)
	PCORI (Patient Centered Outcomes Research Institute)	8/01/2019	07/31/2024
	SAFE CT: Software, Actionable Feedback, and Education for CT: To help institutions optimize their radiation doses		$ 1,400,000 total

To adapt the tools we developed to provide feedback to a large number of institutions on radiation doses for CT. To work with diverse stakeholders to enhance their widespread dissemination and implementation of these tools. Our goal is to widely disseminate and implement these results across as many institutions that perform CT scanning as possible

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2.	PI		
	NIH	03/01/2015	12/1/2023
	Risk of Cancer in Childhood and Adolescence Associated with Medical Imaging	$ 1,834,410 direct/yr 1	$ 10,600,000 total

The primary analysis is ongoing and will be completed before 12/1/23. The no cost extension ended in 2022, but the work is not yet completed. If the results are positive we will submit a grant to continue collecting outcome data and complete analyses

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3.	Co-Principal Investigator. Contact PI: Dr. Gould, Kaiser Foundation Research		
	Patient Centered Outcomes Research Institute (PCORI)	04/01/2015	06/01/2024
	Pragmatic Trial of More versus Less Intensive Strategies for Active Surveillance of Patients with Small Pulmonary Nodules		$ 14,458,936 total

4.	UCSF PI, Subaward	10% % effort	Mazonson (PI)
	NCI	09/01/2023	8/31/2025
	The Alara Imaging Gateway: Linking Electronic Health Records And Radiology Imaging Exams To Report On A National Quality Measures To Reduce Cancer Risk From CT (The Alara Imaging Gateway)	$ 196,000 direct/yr 1	$ 2,400,000 total

The focus of the award is to develop reporting capacity for a new CMS adopted radiation dose and image quality electronic quality measure, and to develop automated feedback to help hospitals optimize their doses

I am leading the UCSF subaward to develop approach for providing insight to hospitals to allow them to optimize dose

RESEARCH AWARDS - PAST

1.	PI		
	Centers for Disease Control and Prevention (CDC)	09/30/2012	09/29/2014
	PEDS CT-DOSE: Pediatric CT Dose Optimization and Standardization Endeavor	$ 500,000 direct/yr 1	$ 500,000 total

2.	PI		Smith-Bindman (PI)
	University of California Office of the President, CHQI	07/01/2011	07/01/2014
	Standardization And Optimization Of Computed Tomography Patient Radiation Dose Across The University of California Medical Centers.	$ 250,000 direct/yr 1	$ 750,000 total

Prospective study across the five University of California Medical Centers to Standardize and reduce the radiation use for CT

3.	Co-Investigator. PI Solberg, Health Partners.		
	Patient Centered Outcomes Research Institute (PCORI)	07/01/2012	06/30/2014
	Measuring Patient Outcome from High Tech Imaging Studies	$ 250,000 direct/yr 1	$ 500,000 total

4.	PI		
	AHRQ	10/01/2010	09/30/2013
	RCT of US versus CT for Patients in the ED with Suspected Renal Colic	$ 4,830,368 direct/yr 1	$ 9,210,000 total

5.	ULI RR024131-01	Co-Investigator		
	NIH		09/30/2006	06/30/2011
	Clinical and Translational Science Institute (CTSI)			
6.		PI		
	NIH / R21		04/01/2009	03/31/2011
	Risk of Cancer with Incidental Findings Identified on US Imaging			$ 317,000 total
7.		Co-Investigator		
	NIH		10/01/2005	09/30/2010
	Biological Basis of Breast Density and Breast Cancer Risk			
8.		PI		Smith-Bindman (PI)
	NIH/R21		09/01/2008	08/31/2010
	Radiation Exposure from Medical Imaging: are Doses in Carcinogic Range?			$ 317,000 total
9.	EB004079-01A2	Co-Investigator		
	NIH		04/01/2006	03/01/2009
	Statistical Methods for Evaluation and Validation of Diagnostic Tests			
10.		PI		
	UCSF, Deans Office		01/01/2008	09/30/2008
	Radiation Exposure from Medical Imaging: are Doses in Carcinogic Range?			$ 91,000 total
11.	BC022339	Co-Investigator		
	Department of Defense/USAMRC		05/01/2003	04/30/2007

Prepared: March 9, 2024

Blueprint for Regional Excellence in Breast Cancer Care			$ 6,900,000 total
12. 9PB-0205	PI		
California Breast Cancer Research Program		07/01/2003	02/01/2007
Racial Disparity in Breast Cancer Mortality			$ 583,287 total
13.	PI		
Women's Health Research Center, UCSF		01/01/2002	12/01/2006
Down Syndrome Screening in the US			$ 70,000 total
14.	PI		
DOD/BC980769		10/01/1999	07/01/2005
Outcomes of Screening Mammography in Elderly Women			$ 725,515 total
15. K07 194603649A6	PI		
NIH		09/01/1999	06/01/2005
Outcomes of Screening Mammography in Elderly Women			$ 635,687 total
16. U01 CA63740	Director		
NIH		04/01/2000	03/31/2005
Physician Predictors of the Accuracy of Screening Mammography			$ 115,022 total
17. U01 CA63740	Co-Investigator		
NIH		04/01/2000	03/31/2005
San Francisco Mammography Registry: A Research Resource			$ 3,100,000 total
18. U01 CA63740	Director		
NIH		04/01/2000	03/31/2005
Validation of the Medicare Screening Algorithm			$ 80,903 total

19.		PI		
	Society of Radiologists in Ultrasound		04/01/2001	04/01/2004
	Physician Variation in Ultrasound Accuracy			$ 30,000 total
20.		PI		
	Society of Radiologists in Ultrasound		04/01/2001	04/01/2003
	Prenatal Ultrasound for Detection of Birth Defects and Chromosome Abnormalities			$ 40,000 total
21.		PI		
	Radiologic Society of North America		07/01/2000	06/01/2001
	U.S. U.K Comparison of The Accuracy of Screening Mammography		$ 40,000 direct/yr 1	
22.		PI		
	Radiologic Society of North America		07/07/1999	06/01/2000
	Prenatal diagnostic ultrasound for the detection of chromosomal abnormalities		$ 35,000 direct/yr 1	
23.		PI		
	Patient Centered Outcomes Research Institute (PCORI)		09/02/2013	08/31/2016
	UCSF CT Radiation Dose Registry to Ensure a Patient Centered Approach for Imaging		$ 492,163 direct/yr 1	$ 2,069,365 total
	Collaboration across the US and Europe to create benchmarks and standards for CT by pooling data from a large number of hospitals and outpatient facilities.			
24.	CA125036-04	PI		Smith-Bindman (PI)
	NIH/K24		09/01/2008	06/30/2015
	Mid Career Development Award: Risk of Cancer Associated of Incidental Findings		$ 172,000 direct/yr 1	$ 868,632 total
25.		PI		

	NIH	07/02/2014	12/31/2020
	CT DOSE Collaboration: Partnership for Dose	$ 1,140,000 direct/yr 1	$ 7,900,000 total

26.	CMS: 1V1-18-002-061598/ P0530892 PI		Smith-Bindman (PI)
	Center for Medicare and Medicaid Services (CMS)	9/14/2018	12/31/2021
	DR CTQS: Defining and Rewarding Computed Tomography Quality and Safety		$ 4,990,358 total
	The focus of the proposal is to develop a suite of quality measures for Computed Tomography (CT) that focuses on radiation dose and image quality that CMS can be used in the quality pay for performance program.		

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2012 Merry, MD et al. Breast Cancer Risk from Medical Imaging Including Computed Tomography (CT) and Nuclear Medicine among Females Enrolled in a Large Integrated health Care System manuscript in preparation. Presented at the Radiological Society of North America Annual Meeting, Chicago, IL, 2012

2012 Mongan, et al. Improving Efficiency of Pulmonary Embolism Testing in Young Female patients manuscript in preparation. Presented at the Radiological Society of North America Annual Meeting, Chicago, IL, 2012

OTHER CREATIVE ACTIVITIES

1. Radiation Safety and CT: Virtual Symposium Director - Innovative On-line Interactive Teaching Classes (May 2012)
The creation of this meeting was an important educational activity for me during 2013. It involved a multidisciplinary meeting with over 100 lectures, 10 live interactive sessions/chat rooms and over 500 registrants enrolled in the meeting during the live days. The meeting was new in format and content. The meeting essentially broke even financially, with an approximately $5,000 profit.

2. 2017 Know Your Dose (see http://knowyourdose.ucsf.edu/), an on line educational resource for patients. This provides extensive education for patient and includes video stories of patients sharing their experiences

3. 2023 UCSF Radiation Safety in Computed Tomography Virtual Symposium 2023. This was a 3 day virtual meeting focused on CT. There were 41 new lectures with interactive Q and A for each.

Exhibit B

Rebecca Smith-Bindman
Materials Considered

1. "A Survey of the Long-Term Effects of Talc and Kaolin Pleurodesis." *British Journal of Diseases of the Chest* 73 (1979): 285–88.
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Exhibit C

Rebecca Smith-Bindman, MD
Medical Legal Testimony in last 5 years

Date: February 7, 2019 and February 8, 2019
Johnson& Johnson Talcum Powder Products Marketing, Sales Practices and Product Liability Litigation MDL No. 2738

Date: August 26, 2021 and August 27, 2021
Ellen Kleiner v. Johnson & Johnson, et al.
Court of Common Pleas, First Judicial District of Pennsylvania

Date: October 10, 2021
Johnson & Johnson Talcum Powder Products Marketing, Sales Practices and Product Liability Litigation MDL No. 2738

Date: March 20, 2024
Johnson & Johnson Talcum Powder Products Marketing, Sales Practices and Product Liability Litigation MDL No. 2738

Hourly Rate: $1,000/hour